Program Description
Animal Care and Use Program

Cincinnati Veterans Affairs Medical Center
VA-114

Department of Veterans Affairs

3200 Vine Street (b)(6), Cincinnati OH 45220

November 29th, 2018

Site Visit: February 7th, 2019

(b)(6) **and** (b)(6)

For

AAALAC International

3/17

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Program Description

Instructions for Completing and Submitting the Program Description for the Institutional Animal Care and Use Program

Section 1. Introduction

A. State the name of the program unit and, if applicable, its parent organization. List all organizations (schools, centers, etc.) included within the program unit.

The unit described in the present document is the Cincinnati Veterans Affairs Medical Center (CVAMC) Research Service. Our Veterans Affairs Medical Center (VAMC) Research Service supports 22 Veterans Affairs (VA) funded investigative programs using animals. Its total VA-supported research budget has remained at about 5 million dollars over the last three years.

Within a VAMC, the Research Service is unique among Services in that it receives funding directly Central Office VA Research and Development. The dollar amount of this support is directly related to the competitiveness of the investigators in peer review, a process identical to that for National Institutes of Health (NIH) grants. In addition, VA Central Office supplies a certain amount of "common resource" funding to support the administrative and common resource scientific components including the Veterinary Medical Unit (VMU). This funding is prorated for each center in relation to its overall levels of VA research funding. Additional scientific programs in our Research Service are supported either by NIH grants or pharmaceutical company grants and private nonprofit organizational support.

The CVAMC and its Research Service is fortunate to be located in close proximity to its Affiliated Institution, The University of Cincinnati (UC) College of Medicine. This allows for a degree of common use of resources and a closer relation between the facilities and staff of the two respective institutions.

B. Give a brief overview of the institution, its purpose and how the animal care and use program relates to the mission of the institution.

CVAMC consists of 2 divisions located in Cincinnati, Ohio and Fort Thomas, Kentucky serving 17 counties in Ohio, Kentucky, and Indiana. CVAMC operates six Community Based Outpatient Clinics located in Bellevue, KY; Florence, KY; Lawrenceburg, IN; Hamilton, OH; Clermont County, OH; and, Georgetown, OH.

The main campus of the CVAMC is classified with a complexity ranking of a 1-b clinical referral facility. It is an affiliated teaching hospital, providing a full range of patient care services, with state-of-the-art technology as well as medical education and research.

Comprehensive health care is provided through primary care, specialty outpatient services and tertiary care in areas of medicine, surgery, psychiatry, physical medicine and rehabilitation, neurology, oncology, dentistry, women's health and geriatrics. The Medical Center is the VISN 10 referral site for neurosurgery and brachytherapy.

The CVAMC has an active affiliation with the UC College of Medicine. The CVAMC is connected functionally to the University. Over 100 University residents, interns, and students are trained at the CVAMC each year. There are also over 30 other academic affiliations involving dentistry, pharmacy, nursing, social work, and psychology.

The Veterans Health Services and Research Administration's primary mission is to provide quality medical care to its veteran patients. Its research program contributes importantly to this mission by providing facilities and funding for research activities that aid in the recruitment and retention of quality physicians, through an environment that supports the research efforts of VA staff, and by assisting investigators in developing new research programs. Since many clinical procedures, drugs, etc., are first tested for efficacy with animal subjects - and valid data from such studies demand the use of animals receiving high quality care - the animal care and use program of our Research Service serves as an integral part of the Veterans Health Services and Research Administration's mission.

C. Note that AAALAC International's three primary standards are *the Guide for the Care and Use of Laboratory Animals* (*Guide*), NRC, 2011; the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (*Ag Guide*), FASS, 2010, and the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Council of Europe (ETS 123). Other regulations and guidelines used (U.S. Department of Agriculture (USDA), Public Health Service (PHS) Policy, Good Laboratory Practice (GLP), Canadian Council on Animal Care (CCAC), etc.) may also apply. Describe which of the three primary standards and other regulations and guidelines are used as standards for the institutional animal care and use program and how they are applied. For example, an academic institution in the United States with an Office of Laboratory Animal Welfare (OLAW) Assurance may use the standards of the *Guide* and PHS Policy for all animals, the Animal Welfare Act regulations for covered species, and the *Ag Guide* for agricultural animals used in agricultural research and teaching (see also *Guide*, pp. 32-33). In the European Union, the standards applied might be the *Guide*, ETS 123, Directive 2010/63, and any country-specific regulations.

We have an OLAW Assurance (A3446-01). Therefore, we follow the standards of the *Guide for the Care and Use of Laboratory Animals (Guide)*, NRC, 2011 and PHS Policy for all animals, and the Animal Welfare Act regulations for USDA covered species.

D. Describe the organization and include an accurate, current, and detailed organizational chart or charts (see **Appendix 4**) detailing the lines of authority from the Institutional Official to the Attending Veterinarian, the Institutional Animal Care and Use Committee/Oversight Body (IACUC/OB), and the personnel providing animal care.

Please include the title, name (*Note:* For individuals whose information is publicly available, provide the titles and names; for individuals whose information is not publicly available, you may provide titles only.), and degree (if applicable) of each individual at the level of supervisor or above. Names of animal care staff below the title of supervisor need not be included, but the titles and number of animal care personnel under each supervisor should be included. If animal care responsibility is administratively decentralized, including the management of satellite housing areas/locations, the organizational chart or charts must include all animal care programs, indicating the relationship between each administrative unit and personnel, the Attending Veterinarian, and the Institutional Official.

Appendix 4 provides an organization chart that describes the interrelations between Research Service, the Veterinary Medical Unit (VMU) within Research Service and the rest of the Medical Center. As can be seen, veterinary guidance is supplied by the Veterinary Medical Consultant (VMC). The Research Service functions within the CVAMC. Its Director is the Associate Chief of Staff for Research (ACOS/R) who, through the Chief of Staff, is responsible to the Medical Center Director. The IACUC, VMU, Safety Committee, Research and Development Committee and Administrative Office are within the Research Service and report to the ACOS/R. Administratively, the Research Service bears a unique relation to the rest of the Medical Center in receiving its funding independently directly from VA Central Office Research Service.

Research Service is also assigned designated Medical Center space. The disposition of this space is determined by the Research Service Space Subcommittee of the Research and Development (R&D) committee. Research Service is also assigned full responsibility for the direction of the VMU. This responsibility is carried out, in part, through the Institutional Animal Care and Use Committee (IACUC) which provides an oversight function ensuring the quality of care and all parameters of animal use in Research Service. All research protocols which require animal use must be approved by the IACUC prior to initiation of study. Appointment to the IACUC is approved by the institutional representative, CVAMC Director.

E. Identify the key institutional representatives (including, but not limited to, the Institutional Official; IACUC/OB Chairperson; Attending Veterinarian; animal program manager; individual(s) providing biosafety, chemical hazard, and radiation safety oversight; etc.); and individuals anticipated to participate in the site visit.

The following institutional representatives will participate in the AAALAC site visit:

(b)(6)
3200 Vine St.
Cincinnati OH, 45220
(513) 861-3100 (b)(6)

(b)(6)
3200 Vine St.
Cincinnati OH, 45220
(b)(6)

(b)(6)
3200 Vine St. #151
Cincinnati OH, 45220
(b)(6)

(b)(6)
3200 Vine Street #151
Cincinnati OH, 45220
(b)(6)

(b)(6)
University of Cincinnati
(b)(6)
Cincinnati, OH 45267

(b)(6)
3200 Vine St. (b)(6)
Cincinnati, OH 45220
(513) 861-3100 (b)(6)

(b)(6)
Cincinnati, OH 45267
(b)(6)

(b)(6)
3200 Vine St. (b)(6)
Cincinnati OH, 45220
(513) 861-3100 (b)(6)

(b)(6)

3200 Vine Street(b)(6)
Cincinnati, OH 45220
(b)(6)

(b)(6)

3200 Vine Street/ IH&S
Cincinnati, OH, 45220
(513) 861-3100 ext(b)(6)

(b)(6)

3200 Vine Street(b)(6)
Cincinnati OH, 45220
(b)(6)

F. Briefly describe the major types of research, testing, and teaching programs involving animals and note the approximate number of principal investigators and protocols involving the use of animals. As mentioned in the instructions, please complete **Appendix 5** (Animal Usage) or provide the information requested in a similar format as an Appendix.

Our VA Research Service sponsor projects involving biomedical research primarily funded through the VA Merit Review peer review process or NIH funding. Presently, current funded projects are supported in Chronic Obstructive Pulmonary Disease, prostate cancer, renal cancer, breast cancer, skin cancer, infectious diseases, autoimmune disease, psychiatry, post-traumatic stress disorder, pulmonary medicine, renal function, biliary disease, among others. None of our VA facilities or animals is used for the purposes of teaching or instruction. There are currently 14 approved animal component of research protocols (ACORPs) and 8 active animal protocol specific Standard Operating Procedures.

See Appendix 5 for "Animal Usage".

G. Note the source(s) of research funding (grants, contracts, etc.) involving the use of animals.

The VA medical center receives federal funding from NIH and Department of Defense (DOD). They also receive funding from VA Merit grants and through foundation / department funded projects.

H. List other units (divisions, institutes, areas, departments, colleges, etc.) of your organization that house and/or use animals that are not included in this Description. If

any of these are contiguous, physically or operationally (e.g., same IACUC/OB, same animal care staff), with the applicant unit, describe the association. Explain why such units are not part of this program application.
Note: Questions regarding this section should be forwarded to the AAALAC Office.

Our VA Research Service does not maintain other on or off-site animal care units beyond those described in this description for animal holding.

I. Contract Facilities: If the institution contracts for animal care facilities or services for animals owned by the institution, the contractor and its AAALAC International accreditation status must be identified. If a contractor's animal care and use program is not accredited by AAALAC International, a brief description, following this Program Description outline, of the relevant contractor's programs and facilities must be provided. In addition, the species and approximate average number of animals housed in the contract facilities and the approximate distance between the institution's animal facility and the contract facility must be noted. Incorporation of the contractor program into the site visit schedule will be discussed with institutional representatives. If the institution does not contract for animal care facilities or services, so note.

None

J. Note other relevant background that will assist reviewers of this report.

The Cincinnati VA Research Service occupies (b)(6) that provides space for conventional and ventilated animal housing and care. The ground floor of (b)(6) provides 21 rooms totaling 2010 net square feet of space for animal housing and 2980 net square feet for support space, totaling 4990 square feet. Rodents are housed in (b)(6) A line drawing of the (b)(6) animal care facility and room (b)(surgery room is provided in Line Drawings Appendix 3.

The new addition to our research space is located in the ground floor of (b)(6) The space is expected to be turned over to us in December 2018. (b)(6) provides 5 holding rooms totaling 1,600 square feet of space for animal housing and 6,000 square feet for support space/circulation, totaling 7,600 net square feet. Rodents will be housed in (b)(6) (b) 4 animal holding rooms, a quarantine room, a procedure room with a rodent surgery suite, cage washing and autoclaving room as well as a necropsy/histology room.

A line drawing of (b)(6) VMU, (b)(6) Procedure/Surgery and room (b)(6 Necropsy and Histology, is provided in the Line Drawings Appendix 3.

Section 2. Description

I. Animal Care and Use Program

A. Program Management

1. Program Management Responsibility [*Guide*, pp. 13-15]

a. The Institutional Official [*Guide* pp. 13-14]
Describe how program needs are clearly and regularly communicated to the Institutional Official by the Attending Veterinarian, IACUC/OB, and others associated with the program.

The Institutional Official (IO) meets with the ACOS/R, AV/VMC , IACUC Chair, and Managing Director of VMU semi-annually. The IACUC report of semiannual inspection and program review is submitted to the IO on behalf of the IACUC along with inspection documents identifying minor and major deficiencies and corrective actions taken. The information is transmitted either by e-mail, hard copy, phone call and/or meetings in person for signatures. In addition, there is a direct line of communication between the VMC, the IACUC, ACOS/R and the IO via research service program support.

b. Role of the Attending Veterinarian [*Guide*, p. 14]

i. Describe the institutional arrangement for providing adequate veterinary care. Although individual name(s) and qualifications will be described below, identify by title the veterinarian(s) responsible for the veterinary care program, including:

- a list of responsibilities
- a description of the veterinarian's involvement in monitoring the care and use of laboratory animals
- the percentage of time devoted to supporting the animal care and use program of the institution if full-time; or the frequency and duration of visits if employed part-time or as a consultant.
  Note: If preferred, this information may be provided in a Table or additional Appendix.

Veterinary Care is available 7 days a week. (b)(6) is the part time, (b)(6) His full-time position is at UC, which is in close proximity to the VA, should an emergency arise. He is available by phone at all times. (b)((b)(6) visits and inspects the VMU at least once a month as well as if there is a sick animal or any issue to check on or for any additional site visits or inspections. Arrangements have been made with (b)(6) at the UC Laboratory Animal Management Service (LAMS), to provide emergency care should (b)(6) not be available.

(b)(6) general duties are as follows:

1. Veterinary care of rodents – In the instance that animals require direct treatment by a veterinarian, not the VA staff (up to 2 hours per month)
2. Laboratory and Diagnostics - Execution of the disease and surveillance program in the VMU – sentinel processing (up to 2 hours on a quarterly schedule)
3. General Care of animals - Facility inspections (required no less than once per month but up to 4 times per month), reviewing and signing health reports; reviewing and approving imports of animals from other institutions and/or approving health status for sending animals out (up to 6 hours per month)
4. Attend monthly Institutional Animal Care and Use Committee (IACUC) meetings, serving as a voting member - Includes semi-annual inspections; provide professional guidance and technical support to the facility's investigators in planning, executing, and directing R&D activities using animals (including performing mandatory veterinary consultations/pre-review of all new protocols and review of any modifications that need veterinarian input) (average of 2 hours per month)
5. Attend post semi-annual inspection meeting with the IO, ACOS/R and the IACUC chair to discuss concerns and outcomes reported in the semi-annual facility inspection and program review (1 hour every six months)
6. Document Review: Review monthly vet reports for the IACUC generated by the VMU Managing Director, and miscellaneous document review; participate in mandated semi-annual IACUC inspections of the animal facilities and the animal care and research program; assist in annual review of the station Animal Care and Use SOP; review and edit reports to oversite entities (OLAW or USDA, PHS) prior to submission of these reports or renewals (average of 3 hours per month)
7. Assist in guiding the facility in preparations for AAALAC accreditation site visits and in reviewing Program Description documents for AAALAC and participating in the site visits (occurs every 3 years) and any compliance visits by other regulatory agencies (varies in frequency). These reports would be initially prepared by the Managing Director of the VMU. (average of 1 hour per month)
8. Serve as a source of guidance on animal research regulations, guidelines, per diem rates and prevailing standards; assisting Managing Director in generating new SOP's when/if necessary
9. Plans, advises, oversees and monitors handling and restraint, anesthetics, analgesics and tranquilizer drugs, and methods of euthanasia, surgical and post-surgical care. He conducts: promotion and monitoring of animal's physical and psychological well-being
10. After Hours, weekend and holiday availability in the case of an emergency

(on site or by phone) – any emergency situations would first be routed through the Managing Director

11. Provide a written invoice detailing the services provided at each visit to the VA as well as animal health checks conducted and a summary of any findings.

Veterinary Care Protocol:
The AV/VMC has access to VMU. Daily monitoring of animals housed in dedicated vivarium is performed by the VMU animal care staff and reported to the Managing Director of VMU. Medical records are kept on all sick animals, except when an alternative description is present describing the expected illnesses in the animals due to a research intervention. Medical records include the animal ID# or cage #, and the nature of the illness. In addition, these forms are used to report all found dead rodents. Once a sick animal is identified, the investigator is contacted. The investigator may choose to euthanize or seek veterinary care for the animal. If the latter is chosen, the Managing Director of VMU is contacted to make an assessment of the animal and then the VMC is immediately contacted. The animal care staff may contact the VMC directly. The VMC provides a plan for treatment and ensures the completion of that plan. The VMC and IACUC assess colony health by review of the mortality and morbidity rate at the monthly IACUC meetings.

ii. List others (e.g., Principal Investigators, veterinarians serving as Principal Investigators, veterinary faculty/staff, technical staff, farm managers) who have a *direct role in the provision of veterinary care* and describe their responsibilities. The Organizational Chart(s) provided in **Appendix 4** must depict the reporting relationship between these individuals and the Attending Veterinarian.
Note: If preferred, this information may be provided in a Table or additional Appendix.

All animal care technicians are responsible for daily examination of animals. They or a designated technician in the investigators laboratory are responsible for treatment of animals. The Managing Director of the VMU is contacted immediately about any sick animal to assess the situation. She then contacts the veterinarian for a plan of treatment unless it is to be immediately euthanized by the laboratory staff or technician. All animal users have direct reporting oversight by the Managing Director and the VMC. See Appendix 4

c. Interinstitutional Collaborations [*Guide*, p. 15]
Describe processes for assigning animal care and use responsibility, animal ownership and IACUC/OB oversight responsibilities at off-site locations for interinstitutional collaborations.

All animal care is conducted on site at the VMU facility. Animals transferred to other facilities are considered the property of the receiving institution and are treated under their protocol by their veterinarians. We have no subcontracts for animal care at other facilities. IACUC oversight is performed by the associated institutions, and semi-annual reports are provided for VA IACUC oversight. There are MOU's in place between VA and UC (signed 9/29/16) and VA and Cincinnati Children's Hospital Medical Center (CCHMC) (signed 6/28/16) for the oversite of animals and the judgement of their IACUC's to be acceptable for VA research animals housed offsite.

2. Personnel Management

a. Training, Education, and Continuing Educational Opportunities

Describe *how* the IACUC/OB provides *oversight* and *evaluates the effectiveness* of training programs and the assessment of personnel competencies. Describe how training is documented.
Note: Do not include details about the training program, which should be described in the following sections.

The VA Research Office oversees that all Talent Management System (TMS) and CITI training are completed and to update for all individuals on a protocol depending on species and IACUC affiliation. TMS is annual training and CITI is due every 3 years. This information is then reviewed and approved by the IACUC.

A database of those investigators, fellows and students undergoing training is maintained. All training must be completed by all research team members prior to approval of a new protocol by the R&D Committee. Research team training will be reviewed annually at the time of submission of a new protocol, modification or continuing review to confirm compliance. Annual continuation will be approved only upon completion of all training requirements by all team members involved in the research protocol. Research Service will maintain research personnel certification files, which contain the curriculum vitae of each principal and secondary investigator, and records documenting the training and experience of all research and animal care staff members. This ensures that all involved personnel have adequate knowledge and ability to perform their duties of animal care, use, and treatment. Effectiveness of the program is evaluated during the semi-annual inspection when animals, personnel, programs, and facilities are inspected.

i. Veterinary and Other Professional Staff [*Guide*, pp. 15-16]

For the Attending Veterinarian and other individuals having a direct role in providing veterinary medical care (veterinarians, other professional staff listed above, private practitioners, etc.), provide: name, credentials (including degrees), and a description of their qualifications, training, and continuing education opportunities.
Note: Please do not provide curriculum vitae of personnel; if preferred, this information may be presented in a Table or additional Appendix.

(b)(6)

Attending Veterinarian/Veterinary Medical Officer: 17 years' experience in veterinary medicine; 13 years' experience in laboratory animal medicine with 2.5 years' serving as Assistant University Veterinarian and 3 years' serving as Assistant Director of Veterinary Services; USDA accredited. Continuing education – 2018 National AALAS; 2016-2018 Charles River Lecture at UC; 2016 National and District 5 AALAS Journal reviewer (e.g., Comparative Medicine, JAALAS, JoVE); Web-based/online trainings (e.g., JAX labs, CRL lectures); LAMS CE classes and wet labs; and UC EHS/IACUC/OHS online trainings.

(b)(6) certified (2003), (b)(6) (b)(6) 20+ years of experience in laboratory animal care technology including 2 years' experience in a research laboratory setting, 5 years as an animal technician and 13 years in a Supervisory capacity. She is a 20-year Member of national AALAS and is a board member of the Committee on Technician Awareness and Development (CTAD), an active member of the Laboratory Animal Management Association (LAMA) as well as a 13-year member of the Southern Ohio Branch (SOB) where she has been serving on the board for 4+ years and she regularly attends AALAS national meetings. (b)(6) holds a Bachelor's degree in business management.

(b)(6)

(b)(6) for Cincinnati VA, Attending Veterinarian and Director at The University of Cincinnati and Attending Veterinarian at the EPA in Cincinnati since Jan 2017: 26 years' experience in veterinary medicine; 13 years' experience in laboratory animal medicine; 10 years' experience serving as AV and Director; USDA-accredited; AAALAC ad hoc Specialist. Continuing education – 2015 Scientists Center for Animal Welfare (SCAW); Journal review (e.g., Comparative Medicine, JAALAS); Web-based/online trainings (e.g., NABR); LAMS CE classes and wet labs; and UC EHS/IACUC/Occupational Health and Safety (OHS) online trainings; 2017: PRIM&R's 2017 IACUC Conference; 2018: PRIM&R's 2018 IACUC Conference.

ii. Animal Care Personnel [*Guide*, p. 16]

1) Indicate the number of animal care personnel.

The CVAMC employs 1 full-time Managing Director and 1 full time animal caretaker: (b)(6), 20+ years' experience, RLAT certified with a BS in business management, and (b)((b)(6) 33+ years' experience. The CVAMC also employs 2 part-time animal caretakers, LW 44+ years of experience, along with SK with less than 1year experience.

2) Summarize their training, certification level and type, experience, and continuing education opportunities provided.
Note: If preferred, this information may be provided in a Table or additional Appendix.

Continuing Education is provided by the VMC and the Managing Director of the VMU to the VMU personnel at the staff meetings, any time new training is required, and through the CITI training program. AALAS certifications are offered but not required. Currently only the Managing Director holds an RLAT AALAS certification.

Continuing education opportunities: Southern Ohio Branch AALAS presentations, CE classes and online trainings.

The Managing Director of the VMU and the VMC are available to staff and frequently provide individual instruction regarding technical procedures or other training needs. Technicians must complete the TMS training annually along with the animal specific training in CITI Program every 3 years.

iii. The Research Team [*Guide*, pp. 16-17; 115-116; 122; 124]

1) Describe the *general mechanisms* by which the institution or IACUC/OB ensures that research personnel have the necessary knowledge and expertise in the animal procedures proposed and the species used.

All research staff and graduate students who use animals are required to receive VMU training by the Managing Director of the VMU prior to being given access to the facility and attend annual training given at staff meetings. In addition, all dual appointed employees with UC are required to receive 1 hour of training in the Humane Care and Use of Laboratory Animals once every 3 years. (b)(6), (b)(6) the (b)(6) (b)(6) provides a pre-review of the Animal Component of the Research Protocols (ACORPs) submitted and will provide specific training as needed for personnel on the protocol.

New Principal Investigator and other research personnel with a significant history of work with the species requested, which has been documented by the publication of multiple, peer-reviewed reports of research involving the requested species, are required to submit evidence of experience/training.

All new personnel must contact the Managing Director so that a general orientation and protocol-specific, and/or species-specific training can be arranged.

Research Service can coordinate additional assistance with species-specific or protocol-specific techniques whenever additional individual instruction is requested, and/or required by the IACUC.

a) Briefly describe the content of any required training.

New PI's and other research personnel are required to complete all mandatory training via the TMS system which includes the following modules:

1. VA Privacy and Information Security Awareness and Rules of Behavior (required every 12 months on anniversary date of completion), TMS Course # 10176
2. Safe Use of Anesthetic Gases, TMS Course #4188392
3. Blood borne Pathogens, TMS Course #11430
4. Preparing for Emergencies and Disasters: All Hazards, TMS Course #3249
5. Electrical Safety, TMS Course #11432
6. Hospital Fire Safety, TMS Course #11433
7. Hazardous Materials Communication, TMS Course #11434
8. Standard Precautions, TMS Course #11436
9. Tuberculosis Prevention, TMS Course #11437
10. Patient Rights, TMS Course #11443
11. Prevention of Workplace Harassment/NO FEAR, TMS Course #8872
12. Workplace Violence Awareness, TMS Course #11452
13. Understanding Cultural Diversity, TMS Course #11460
14. VHA CO Compliance & Business Integrity (CBI) Awareness Training, TMS Course #7318
15. VHA Mandatory Training for Trainees (WOC's Only, and a one-time completion requirement), TMS Course # 3185966

Also have to complete all assigned CITI training depending on species and association with research service (general training and mouse, rat, and/or hamster, IACUC modules) which includes the following:

1. Essentials for IACUC Members
    a) Essentials for IACUC Members: Introduction (ID: 1833)
    b) Federal Laws, Policies, and Guidelines (ID: 17662)
    c) IACUC and IACUC Member Responsibilities (ID: 1834)
    d) IACUC Membership Requirements (ID: 1835)
    e) Quorum, Alternate Members, and Telecommunications (ID: 1838)
    f) The IACUC, CEO, and IO (ID: 1836)
    g) Protocol Review (ID: 1839)
    h) Suspending Animal Activities (ID: 1837)
    i) Types of IACUC Review: Initial, Annual, Triennial (ID: 1841)

        - j) Documenting IACUC Actions (ID: 1842)
        - k) Semiannual Evaluations – An Overview (ID: 1843)
        - l) Facility Inspections and Program Review (ID: 1844)
        - m) Identifying, Documenting, and Correcting Deficiencies (ID: 1845)
        - n) Outcomes of Animal Protocol Reviews (ID: 1840)
        - o) Investigating Allegations of Improper Animal Care or Use (ID: 1846)
        - p) Maintaining the Public Trust (ID: 1847)
2. Working with the IACUC
    - a) Working with the IACUC: Introduction (ID: 17660)
    - b) About the IACUC (ID: 17661)
    - c) Federal Laws, Policies, and Guidelines (ID: 17662)
    - d) Planning Research and Completing the Protocol Form (ID: 17663)
    - e) Procedures: Surgery, Antibody Production, and Blood Collection (ID: 17664)
    - f) Personnel and Their Welfare (ID: 17665)
    - g) Special Animal Welfare Considerations (ID: 17666)
    - h) Making Changes to an Approved Animal Use Protocol (ID: 17667)
    - i) Reporting Animal Use Concerns (ID: 17668)
3. Working with Mice in Research Settings
    - a) Introduction to Working with Mice in Research Settings (ID: 1933)
    - b) Research Mandates and Occupational Health Issues (ID: 1934)
    - c) Alternatives Search, Humane Standards, Housing, Source, and Acclimation and Quarantine (ID: 1936)
    - d) Detecting Pain and Distress, Genetics, and Biological Features (ID: 1940)
    - e) Injections, Blood Collection, and Antibody Production (ID: 1943)
    - f) Surgery, Supportive Care and Monitoring, Euthanasia, and References (ID: 1946)
4. Working with Rats in Research Settings
    - a) Introduction to Working with Rats in Research Settings (ID: 1916)
    - b) Research Mandates and Occupational Health Issues (ID: 1917)
    - c) Alternatives Searches, Humane Standards, Housing, and Acclimation and Quarantine (ID: 1919)
    - d) Detecting Pain and Distress, Genetics, and Biological Features (ID: 1923)
    - e) Injections, Blood Collection, Antibody Production, and Pain Relief (ID: 1926)
    - f) Surgery, Supportive Care and Monitoring, Euthanasia, and

References (ID: 1929)

5. Working with Hamsters in Research Settings
    1. a) Introduction to Working with Hamsters in Research Settings (ID: 1984)
    2. b) Research Mandates and Occupational Health Issues (ID: 1985)
    3. c) Alternatives Search, Humane Standards, Housing, Acclimation and Quarantine, Detecting Pain and Distress (ID: 1987)
    4. d) Species/Strains (ID: 1992)
    5. e) Surgery, Supportive Care and Monitoring, Euthanasia, and References (ID: 1996)

- Participates in VMU training with the Managing Director.
- Any requested or required species specific, technique or handling procedures deemed necessary at initial/continual review.
- Euthanasia training for all users of the VMU, documented proficiency by the Managing Director of the VMU.

b) Describe the timing of training requirements relative to the commencement of work.

All training requirements must be met prior to conducting any work in the VMU. Approval of a new or an annual review protocol will not be given approval until all personnel listed have met the training requirements. Training must be up to date annually as well for approval of the PI's annual IACUC progress report.

c) Describe continuing education opportunities offered.

Although most are trained in specific surgical techniques by the PI, individual training is offered to all research personnel involved in survival surgical procedures by the veterinarian. This training includes aseptic procedures, surgical skills (where necessary), and additional training in anesthesia, postoperative monitoring, and analgesia. This training provides the few investigators performing survival surgical procedures with the necessary skills on an individual basis with animal care personnel oversight during the initial procedures. The Managing Director of the VMU and/or the VMC are also is available to train research team members on common animal handling procedures and techniques such as animal handling, blood collection techniques, IP, IM or SQ injections, identification techniques, etc.

Continuing education opportunities offered to research personnel include: IACUC required retraining as part of the IACUC protocol triennial review, Charles River Laboratories and JAX online modules and webinars.

In addition, the Veterinarian and the Managing Director of the VMU conduct any new needed training and overviews of Zoonoses and allergies annually at our all research meeting.

2) Describe the process(es) to ensure surgical and related procedures are performed by qualified and trained personnel, including:

- who determines that personnel are qualified and trained for surgical procedures
- the roles that the Attending Veterinarian and IACUC/OB have in this determination [*Guide*, pp. 115-116]

All persons must have had appropriate training to ensure that good surgical technique is practiced, that is, asepsis, gentle tissue handling, minimal dissection of tissue, appropriate use of instruments, effective hemostasis, and correct use of suture materials and patterns.

People performing and assisting in surgical procedures at the CVAMC have a wide range of educational backgrounds and require various levels and kinds of training before they participate in surgical procedures on animals. Thus, training is personalized for each skill set. For example, persons trained in human surgery might need training in inter species variations in anatomy, physiology, and the effects of anesthetic and analgesic drugs, or in postoperative requirements.

The PHS Policy and the AWRs place responsibility with the IACUC for determining that personnel performing surgical procedures are appropriately qualified and trained in the procedures to be performed. The VMC oversees and conducts surgical training if necessary and/or observes a surgery the first time it is conducted by new lab personnel to ensure proper technique or if there is any concern that there is a need for training based on the IACUC's review of the protocol.

3) Describe the training and experience required to perform anesthesia. [*Guide*, p. 122]

Training and experience is reviewed and verified by the VMC in conjunction with the PI and IACUC review of the ACORP. The PI or a research team member with significant experience in anesthesia may provide training and oversight of research personnel to ensure each person performing anesthesia is appropriately trained. Either the VMC will provide direct training or training through an approved course will be acceptable with documentation of completion of the training prior to full approval of the ACORP.

4) Describe how the proficiency of personnel conducting euthanasia is ensured (especially physical methods of euthanasia). [*Guide*, p. 124]

(b)(6) ill review specific ACORP details with investigators to verify that they have received the appropriate training. For anyone not familiar with the proper methods of euthanasia, training is available by the VMC or Managing Director of the VMU prior to conducting animal work in the VMU. Per VA policy, the Managing Director must witness and document proficiency of euthanasia technique for each animal user at the onset of their work in the VMU.
It is essential that euthanasia be performed by personnel who are skilled in methods for the species in question and that it is performed in a professional and compassionate manner. Death should be confirmed by personnel who can recognize cessation of vital signs in the species being euthanized. When using anesthetics or CO2 euthanasia techniques, a secondary method such as cervical dislocation or puncture of the diaphragm is required to ensure the death of the animal.

See SOP Euthanasia by CO2 VMU 018 (available by request)

b. Occupational Health and Safety of Personnel [*Guide*, pp. 17-23]

i. Institutional Oversight [*Guide*, pp. 17-19]

1) List the institutional entities (units, departments, personnel, *etc.*) that are involved in the planning, oversight, and operation of the institutional occupational health and safety program related to animal care and use (e.g., office(s) of environmental health, institutional health services or clinics (*including contracted health services*), industrial hygienists, Institutional Biosafety Committee(s) and/or Officer(s), Radiation Safety Committee(s) and/or Officer(s).

- Include a brief description of their responsibilities and qualifications.
- If contracted services are used, also include their location (e.g.,remote offices to which personnel must report).

The institutional entities involved are: Research Services, Subcommittee on Research Safety/Institutional Biosafety Committee (SRS/IBC), IACUC, Radiation Safety Committee, Research Safety Officer (RSO), Industrial Hygiene and Safety, Biosafety Officer, and Employee Health (EH).

The Occupational Health Program follows the guidelines set forth by our Research Service in conjunction with the CVAMC Employee Health Service. Those employees who work in the VMU or who have contact with animals must complete an annual health questionnaire. Employees are offered the opportunity for rabies vaccination. Annual TB testing is required and flu shots are encouraged.

The RSO and Employee health nurses and/or doctors work closely with the Research Service to ensure that all employees involved with animals submit the annual health assessments.

The Occupational Health and Safety Program (OHSP) is an important component of CVAMC Institutional Animal Care and Use Program. This program is designed to protect both VA's personnel and the animals. The occupational health program for animal care personnel or persons using animals is provided by the IACUC and EH. The program is announced in training sessions, and is announced in periodic mailings from the IACUC. The ACOS/R is responsible for the overall management of the OHSP. The institution has established a functional OHSP that includes the research program and is consistent with federal, state, and local regulations. The OHSP is available to all personnel who enter the animal facility, including those with infrequent or random access (e.g., maintenance, housekeeping and security staff, and non-affiliated IACUC members).

Subcommittee on Research Safety (SRS)/Institutional Biosafety Committee (IBC): The SRS/IBC is responsible for reviewing all research protocols conducted at the CVAMC facility or by VA personnel with VA funding located off-site, prior to commencement of research activities and at the time of their annual continuing review with respect to application of safety-related standards. The SRS/IBC will provide written notification of the review decisions to the R&DC, Research Service office, and the Principal Investigator (PI). Committee membership requirements, meeting operations, assigned duties, and initial/annual study review requirements are made in accordance with the CVAMC SRS/IBC Standard Operating Procedures (SRS/IBC SOP). The SRS/IBC will ensure coordination with other relevant personnel and/or committees in the review of research protocols (e.g. Radiation Safety Officer, Industrial Hygienist).

The SRS/IBC will conduct an annual review of the SRS/IBC SOP. The results of this review and any updates will be forwarded to the R&DC for approval via the SRS/IBC meeting minutes. The SRS/IBC will review the laboratory inspection reports via the semi-annual Laboratory Biosafety Assessment-BSL-2 checklist and the quarterly Laboratory Safety Inspection Checklist. Results of these inspections and follow-up remediation efforts will be reported to Research Services, R&DC, and applicable investigators. The SRS/IBC will submit candidates for the BSO and the RSO to the R&DC for approval. The SRS/IBC will conduct an annual review of the Emergency Response Plan, the Security Plan and the Emergency Preparedness and Response Drill.

The SRS/IBC reports all research-related workplace injuries/exposures and trends to the MCD/IO, ACOS/R, the R&DC, and other relevant research review personnel and committees. The SRS/IBC will report operational problems or violations of directives to the Research Service Office within 30 days of occurrence or detection, unless SRS/IBC determines that a report has been previously filed by the PI. The SRS/IBC will also review security procedures after a security incident. The SRS/IBC will identify the need for health surveillance of personnel as necessitated by protocol-specific research activities; and if appropriate, advising the R&DC and Employee Health Practitioner as to the need for such surveillance.

Biosafety Officer: BSO develops and participates in programs to promote safe microbiological practices, procedures, and proper use of containment equipment and facilities; stimulates responsible activities among workers; and provides advice on laboratory design. The BSO also participates in regular BSL-2 lab inspections to ensure safe lab practices.

Research Safety Officer: RSO monitors procurement, use, and disposal of chemicals used in the lab. Ensure that appropriate self-inspections are maintained. Provide input to PI's/Supervisors on developing precautions and adequate facilities. Is responsible to know the current legal requirements concerning regulated substances, as provided through Industrial Hygiene & Safety (IH&S) resources. Seek ways to improve the chemical hygiene program.

Radiation Safety Officer: The Radiation Safety Officer is the person responsible for radiological safety in conjunction with the use, handling, and storage of radioactive materials in a program licensed by the Nuclear Regulatory Commission (NRC) or Agreement State.

Industrial Hygienist: IH&S office is responsible for planning, developing, implementing and evaluating the Occupational Health Program at the medical center to identify, control, and eliminate industrial and occupational health hazards. Advises on the status of industrial hygiene programs and recommends changes in the design of work programs to meet new and existing industrial hygiene standards. The IH monitors risks such as noise, air quality and chemical exposure limits by request or annually for spot checks.

2) Describe methods to identify work-related hazards and the processes used to evaluate the significance of those hazards in the context of duties and tasks. Describe both common approaches and differences, if applicable, for categories of personnel such as, but not limited to, researchers, veterinarians, husbandry staff, cage-washing staff, students, housekeeping, physical plant staff, security personnel, IACUC/OB members (including non-affiliated members), contractors, visitors, etc.

[*Guide*, pp. 18-19; see also Chapters 2 and 3 in Occupational Health and Safety in the Care and Use of Research Animals, NRC 1997.].

Written safety protocols detailing the use and disposal of the specific hazardous agents used in the study are required from investigators. All ACORPs that utilize hazardous materials (biological, chemical, physical, radiological) are reviewed by the SRS/IBC and associated safety officers. ACORPs are reviewed and approved by our RSO, the IACUC, and SRS/IBC prior to protocol initiation within the facility. Management of risks is through Industrial Hygiene and Safety office based on common practices recommended locally, statewide and nationally. The safety office provides Material Safety Data Sheets (MSDS) hard copies in the 2nd floor radiology suite, also MSDS hard copies can be found at 1-800-451-8346 or https://www.3eonline.com/EeeOnlinePortal/DesktopDefault.aspx?tabid=53 web site. Personnel involved with hazardous agents must study and sign off on relevant protocols acknowledging their understanding of potential hazards involved and safety measures to be observed. In addition, Standard Operating Procedures outline the personnel protective equipment needed for work under the specific hazardous conditions of the study.

For the safety of animal care staff, any protocol that involves any potential risk such as ABSL-2 studies, the IACUC requires a protocol specific SOP outlining the risks and precautions to take, for the staff to follow, in handling the risk.

3) Describe methods and frequency of reassessing work-related hazards.

If exposure or injury is suspected or occurs, the person is sent directly to EH for an assessment. An incident report is entered via the ASSIST program and any follow up is conducted through EH.

For any hazards that could be repetitive such as exposure to elements, the IH regularly monitors (annual at least) exposure limits on things such as isoflurane and CO2 limits by placing a monitoring badge on an individual to collect the sample, then sends it out to be evaluated.

4) Describe institutional programs or methods used to track and evaluate safety-related workplace incidents, including injuries, exposures, accidents, etc. Include the frequency of such assessments. [*Guide*, pp. 18-19]

Employees must promptly inform their supervisors of exposures and on-the-job injuries/illnesses and complete an initial Work-Related Injury or Illness report within 24 hours of the initial injury/illness. In the event of a medical emergency, medical care can be summoned externally by calling 9-911 or internally by calling 4333. Any and all safety-related or workplace incidents are recorded in the ASSIST program. They are entered and tracked by EH, IH&S and by Management. They are entered and tracked as incidents arise. In addition, any exposure to a hazard involving animals or the animal facilities will prompt a review of work practices, which may include retraining of personnel if deemed necessary.

ii. Standard Working Conditions and Baseline Precautions
The following section pertains to the Occupational Health and Safety Program for all personnel associated with the animal care and use program. Specific information regarding the use of hazardous agents is included in ***subsection iii*** below.

1) Medical Evaluation and Preventive Medicine for Personnel [*Guide*, pp. 22-23] *Note:* Include blank forms used for individual health assessment as **Appendix 6.**

a) Describe who (e.g., personnel assigned to job/task categories in I.A.2.b.i.2) above) receives personal medical evaluation as a component of individual risk assessment. Describe who are ***not*** included and/or exempted from personal medical evaluation. *Note:* Do not include the names of personnel.

Any person requiring and having approved contact with the research animals, such as: researchers, veterinarian, husbandry staff, cage-washing staff and students, are given the initial and annual health assessment for employee health to determine what, if any risk each individual has in working with the animals.

For all personnel or visitors who will have no direct animal contact, are not required to participate in the annual health assessment but are required to take part in the following procedure.

Prior to entry into the VMU, VMU Access Training for Visitors document is given to the individual. This document contains the entry requirements, security requirements and Occupational Health risks that one could come in contact with. Each person is required to read the document and then fill out and sign the last page of understanding. A database and forms are kept on record by the Managing Director of the VMU and renewed annually or as needed. Visitors include but are not limited to: housekeeping, physical plant (Engineering) staff, security personnel (Police), IACUC/OB members (including non-affiliated members), contractors and visitors.

b) Describe provisions for allowing an individual (following completion of individual health and job-related risk assessments) to decline participation in all or part(s) of subsequently available medical and

preventive medicine components of the institutional program, e.g., vaccinations, physical examinations, respiratory protection, as applicable. Provide an estimate (percentage) of personnel associated with the animal care and use program that have declined participation in the medical evaluation program.
Note: Do not include names of the personnel

Per VA regulation 1200.07 Appendix C-4(2), Enrollment in OHSP is prerequisite to approval for access to the VMU for beginning work with animals. Further, per VA regulation 1200.07 (10.b) "Personnel are not permitted to decline immunizations or tests required by the VA facility that are necessary to protect the health of the animals or personnel".

Thus far we have had no one decline participation in the program.

c) Describe provisions for assuring confidentiality of medical information.

Forms are mailed or delivered directly to the EH to ensure confidentiality of medical information. Any further correspondence is between EH and the employee.

d) Describe safety considerations for individuals with incidental exposure to animal care and use (e.g., contractors, personnel working in open laboratories).

Any contractors, engineering staff or other personnel needing to conduct work in the VMU, who have gotten approval to enter, must wear a lab coat or disposable gown and shoe covers. They are offered a mask and gloves if they choose to wear them.

e) Describe general features of the medical evaluation and preventive medicine programs, within the context of work duties, including:

- pre-employment/pre-assignment health evaluation,
- medical evaluations (including periodicity),
- diagnostic tests (e.g., for tuberculosis),
- precautions for working with potentially hazardous species (e.g., nonhuman primates, sheep, venomous species)
- immunization programs, and
- procedures for communicating health related issues.

All persons listed on an ACORP are required to enroll prior to any involvement in animal care and/or animal research. Enrolling means that information is provided to persons included and the person must:
1. Submit the Periodic Animal Exposure Questionnaire to EH
2. Procedures

a. Annually, and usually at the beginning of the fiscal year the Periodic Animal Exposure Questionnaire form must be completed by all animal study personnel and submitted through Research Service to EH. Any persons newly hired or added to a project must complete the Periodic Animal Exposure Questionnaire form at the time they are hired or added. Also, if a person's medical conditions change in the course of the year, the form should be updated at the time of change
b. Occupational Health Risk is evaluated through the review of the ACORP at the time of initial submission and at de novo review. This review will be used by IACUC and other committees to assess risks and make recommendations to the EH service.
c. EH will review the health evaluations in conjunction with the risk assessment and make recommendations to the individual. Medical information is confidential.
d. Individuals determined to be at risk as a result of the OHE form must complete a *Comprehensive Health Assessment* form. At risk individuals are offered comprehensive health services by EH. Personnel are provided the opportunity of receiving vaccines, free of cost, in accordance with current CDC recommendations. These services consist of serologic documentation of immunization with rabies, rubella, rubeola, varicella, hepatitis B, and diphtheria/tetanus vaccines (<10 years prior to initiating animal contact), documentation of a PPD skin test for tuberculosis infection (<3 months prior to initiating animal contact), and if the PPD skin test is positive, documentation of a negative chest radiograph (<6 months from initiating animal contact). These comprehensive health assessments and vaccinations are documented by EH. These forms are mailed or delivered directly to the EH to ensure confidentiality of medical information.
e. EH maintains records of a pre-placement occupational health evaluation for each research and animal care staff member.

Potentially hazardous species: VMU does not house potentially hazardous species (e.g., nonhuman primates, sheep, venomous species).

f) Describe any other entities that provide medical services (e.g., emergency care, after-hours care, special medical evaluation, contracted services). Include a brief description of their credentials and/or qualifications, and how these entities remain knowledgeable about animal- or institution-related hazards and risks.

None

2) **Personnel Training Regarding Occupational Health and Safety** [*Guide*, p. 20]

Describe general educational program(s) to inform personnel about:

- allergies,
- zoonoses,
- personal hygiene,
- physical injuries in animal facilities (e.g., noisy areas, large quantities of chemicals such as disinfectants, ergonomics) or species used (e.g., nonhuman primates, agricultural animals),
- other considerations regarding occupational health and safety.

Include in the description a summary of the topics covered, including:

- Entities responsible for providing the training
- Frequency of training or refresher training

Note: Do not include special or agent-specific training for personnel exposed to experiment-related hazardous agents; this will be provided in **Section iii.3** below.

Information delineating the hazards associated with the use of animals is provided as a portion of the animal care and use training program. All animal users are mandated to complete the online animal training through www.citiprogram.org. This training completion is confirmed by the research administrative offices prior to IACUC approval of a protocol being granted and annually (based on fiscal year) at new submission, progress report or modification to an existing protocol. Additional training is required also, which includes but is not limited to, appropriate sharps handling and disposal, chemical hazards, etc. At the annual meeting, the VMC and the Managing Director of the VMU provides zoonotic, allergy and other pertinent training relative to current topics.

3) **Personal Hygiene** [*Guide*, p. 20; *Ag Guide* pp. 4-5]

a) List routine personal protective equipment and work clothing provided and/or required for animal care personnel, research and technical staff, farm employees, etc.

Animal care and use personnel may wear a full-length uniform or lab coat and, as appropriate, a face mask, gloves, and head or hair cover in animal holding rooms.

To safeguard both research personnel and laboratory animals, the OHSP requires that all personnel with direct animal contact use the following personal protective equipment.

1. Dedicated Clothing and Standard PPE
   a. Surgical scrubs and/or a laboratory jacket and disposable shoe covers at all times (Provided by VMU).
   b. Dedicated clothing should be worn only while working with the animals and it must be laundered on a routine basis.
   c. In designated animal rooms, the use of hair bonnets, gloves, sleeve covers/gowns and masks are required when handling animals in open cages.

2. Specialized PPE
   a) Eye and Face Protection
      1. Protective eyewear (goggles and/or face shields) must be used in any area where there is reasonable probability of eye injury. This includes use of corrosive liquids, injurious radiation (lasers), chemicals and when there is possibility of exposure to secretions, sputum or aerosolization of infectious agents.
      2. Contact Industrial Hygiene & Safety (IH&S) for assistance in selecting appropriate eye protection. Note: Areas requiring the use of eye protection must have a sign posted at the entrance. The sign indicates "EYE PROTECTION REQUIRED"

   b) Hearing Protection
      The noise level in animal research facility areas may reach potentially damaging levels, particularly in cage washing areas. Ear protection is provided whenever noise levels exceed those permissible levels established by the Occupation Safety and Health Administration regulations, or whenever requested by an employee. IH&S ran noise testing and determined that the noise levels are only above acceptable levels when pushing and pulling the cage washing rack in and out of the machine. Hearing protection is provided on both sides of the washer.

   c) Disposable shoe covers (for non-VMU employees) and dedicated clothing, gowns or lab coats are required when working in the animal laboratory facility. Use of these devices limit the risk of transmitting infectious agents into the VMU and additional personal protective equipment (PPE) may be required when animals are housed under specific housing conditions.

   d) Respiratory Protection
      1. The use of disposable masks is recommended to reduce the amount of airborne particulate and allergens that may be inhaled by individuals working with laboratory animals.

2. Once individuals develop allergic symptoms, disposable surgical-style masks are usually not effective, and it is recommended that NIOSH certified dust-mist respirators or filtered air hood devices be used. Effective use of these devices requires fit testing by IH&S.
3. Contact IH&S for assistance with selection of proper respiratory protective equipment.

3. Miscellaneous Safety Equipment
    1. Additional safety practices, and equipment, may be required dependent on ACORP design. For example, investigators working with hazardous agents may be required to institute additional safety practices, as determined by IH&S, and the SRS/IBC
    2. Back injuries are a common hazard for animal research facility employees because of lifting requirements. Employees are to always practice safe-lifting techniques. Back braces shall be available to employees who perform lifting tasks on a daily basis, and tasks need to be made as ergonomically efficient as possible. Whenever possible, hydraulic or electric lifting equipment needs to be used.
    3. Employees who are at risk of crushing foot injuries from heavy objects must be provided steel-toed footwear if deemed necessary.

b) Describe arrangements for laundering work clothing.

The VMU staff launders all lab coats worn in the facility as well as uniforms in a washer and dryer dedicated to the facility.

c) Describe provisions and expected practices for washing hands, showering, and changing clothes, including instances where work clothes may be worn outside the animal facility.

The CVAMC does not have shower facilities in the VMU. Staff is required to change into work scrubs and shoes at the facility either in the office or in the basement locker area. All animal rooms as well as multiple other areas contain sinks for hand washing. Facility clothes are allowed to be worn outside the facility while on VA grounds; however, a clean lab coat must be worn over scrubs when going outside the facility.

Hand washing is expected frequently, when leaving an animal room after cage changing, after cage washing and in any other incidence where there has been exposure to potential contaminants.

Whenever bare hands, arms, neck/face, or head become accidentally or unavoidably contaminated with animal blood, urine, feces, or hair, such contamination should be removed as soon as possible by washing thoroughly with water and soap. When materials enter the mouth or eyes, wash the exposed area with generous amounts of water. Report the incident to EH for further evaluation.

In rare circumstances determined by either the Managing Director of the VMU or VMC, a shower shall be taken before entering the facility at the beginning of the workday and when leaving at the end of the day. Any laboratory staff who are doing work at multiple animal facilities, such as UC or CCHMC and the VA, may NOT go between facilities within a 14 hour overnight time period unless they shower and change clothes.

d) Describe policies regarding eating, drinking, and smoking in animal facilities.

Eating and drinking are prohibited in all animal areas of the VMU, with the exception of the animal caretaker office. Smoking is prohibited throughout the VMU and throughout VA grounds. There are designated smoking shelters provided outside the building. Food storage is available in the caretaker office and in designated refrigerators located in the Research Services area. Food and drinks brought into the caretaker office must be covered and contained while passing through the VMU corridors.

4) **Standard Personnel Protection** [*Guide*, pp. 21-22]

a) Describe facility design features, equipment and procedures employed to reduce potential for physical injury inherent to animal facilities (e.g., noisy areas, large quantities of chemicals such as disinfectants, ergonomics) or species used (e.g., nonhuman primates, agricultural animals).

All biosafety cabinets have adjustment height to avoid back injury; all personnel are recommended to wear non-slip shoes. All personnel are instructed on the proper lift procedures and back braces can be obtained through the IH&S office upon request. A HEPA filtered dump station helps to reduce allergen as do the PIV racks, isolation cages and changing the cages under a class II safety cabinet. Carts are used to transport cages and keep supplies at waist height to minimize bending and lifting. Ear protection is provided for potentially noisy areas such as cage wash. Face shields and safety goggles are provided in areas where mixing and pouring chemicals occurs.

b) Describe likely sources of allergens and facility design features, equipment, and procedures employed to reduce the potential for developing Laboratory Animal Allergies (LAA).

The greatest risk of exposure involves any activity that disturbs the bedding material of the animal generating airborne particles. VA's Animal Care and Use Program consists primarily of rodent species. The most likely source of allergens are from rodent caging. Mice and hamsters are housed in containment caging (e.g., individually ventilated or static microisolator cages). Whenever possible, mouse cages are opened in a hood. Staff handling mice and hamsters wear PPE (sterile gown, cap, mask, gloves). Rats are typically housed in open shoebox cages. Dedicated scrubs or disposable gown and gloves are worn. Respiratory protection is recommended.

The best method to minimize the potential for the development of allergies is to minimize exposure to the allergens. Animal rooms have relatively high air flow, which reduces the concentration of allergens in the air by dilution. The control of the relative humidity to 30-70% also reduces the level of allergens in these rooms. Animals removed to investigator laboratories are placed in environments which permit a much greater accumulation of allergens.

Personnel with known allergies to laboratory animals should be evaluated by the occupational health physician and reevaluated on a regular schedule. At a minimum, personnel with documented laboratory animal allergies should use a dust-mist respirator certified by NIOSH.

Personnel with established allergies to laboratory animals are always at risk of exposure and the reoccurrence of severe disease. Generally, this exposure occurs through contact with contaminated equipment or clothing, or inadvertent and unexpected exposure to the animals during transport. Personnel working with animals must be aware of this potential effect and take steps to minimize exposure of personnel outside the animal facility to allergens. These actions include the wearing of protective clothing (lab coats, etc.) in the animal facility, the transportation of animals in containers/cages designed to minimize allergen exposure (barrier cages), cleaning of equipment exposed to animals prior to removal from the animal facility.

HEPA Filtered Cages and the use of biosafety cabinets to handle, change cages and dump dirty bedding help reduce the exposure risk.

c) Describe likely sources of zoonoses and facility design features, equipment, and procedures employed to reduce potential exposure to zoonoses.

With the number and range of potential zoonotic diseases, it is a reaffirmation of the validity of standard containment techniques that the number of zoonotic diseases transmitted between the laboratory research animals and the research personnel is small. The animals housed at VMU are laboratory-bred rodents and are not likely sources of zoonoses.

Basic handling techniques that we require such as, changing cages in a biosafety cabinet, wearing required/suggested PPE, attention to personal hygiene (e.g. frequent hand washing), and using dump stations to empty dirty cages are all employed to reduce potential exposure.

d) Describe the procedures for the maintenance of protective equipment and how its function is periodically assessed.

All biosafety cabinets and bedding dump stations are inspected and certified annually to ensure they are functioning correctly in accordance with manufacturers' recommendations and regulatory guidance.

e) Respiratory Protection

i) Describe situations where respiratory protective equipment is available or required, such as cage washing facilities, feedmills, etc.

Respiratory protection is recommended for VMU staff working in dirty side cage wash or working in ABSL-2, chemical, or open caging rooms. Respiratory protection (e.g., N-95, PAPR) fit testing is provided for all VMU staff by IH&S upon request.

ii) Describe programs of medical clearance, fit-testing, and training in the proper use and maintenance of respirators.

Currently we have no situations that require respirators. However, if needed, fit testing for respirators is done with our health and safety office and training on the proper use and maintenance of the respirators is provided. Respirators/N95 are available but not required.

iii) Describe how such respiratory protective equipment is selected and its function periodically assessed.

Currently we have no situations that require respirators. If they are, IH&S conducts the fit testing and periodic evaluations.

f) Heavy Equipment and Motorized Vehicles

i) Provide a general list of the types of cage-processing equipment used, such as rack/cage washers, tunnel washers, robotics, and bulk autoclaves. Describe training programs, informational signage, and other program policies designed to ensure personnel safety when working with such equipment.
Note: Details of specific equipment installed in animal facility(ies) are to be provided in **Appendix 15** (Facilities and Equipment for Sanitizing Materials).

Between the 2 animal holding facilities, we have: 1 Bulk sterilizer, 1 double length cage/rack washer, one small cage washer, 1 bottle washer, 1 single length cage/rack washer and 1 pass through autoclave.

As part of our program, policy signs are posted on both sides of the cage washer that describe the safety requirements. These detail how to get out if someone is closed inside and where the emergency stop buttons and pull cables are located, as well as having hearing protection available on both sides of the washer. Any new employees are trained on the safe handling of the machines upon hire by the Managing Director.

ii) List other heavy equipment such as scrapers, tractors, and farm machinery (manufacturer name, model numbers, etc. are not necessary). Describe training programs, informational signage, and other program policies designed to ensure personnel safety when working with such equipment.
Note: If preferred, this information may be provided in a Table or additional Appendix.

No other heavy equipment is utilized

iii) If motorized vehicles are used for animal transport, describe how the driver is protected from exposure to hazards such as allergens or zoonoses and decontamination methods employed. Also describe instances where vehicles may be shared between animal and passenger transport.

The CVAMC does not maintain any motorized vehicles. Transfers between VA and UC are done in UC's climate controlled box truck or cargo van. At UC, Cargo van surfaces (e.g., side panels and bulkhead) are wiped down after each animal transport with a germicidal cloth (e.g., Sani-Wipe cloth). The floor is sprayed with a chlorine dioxide based disinfectant (e.g., Clidox) allowing contact time of 10 minutes.

Fuso box truck cargo area is sanitized after each animal transport and/or between equipment transports. The cargo area is fogged for 30 minutes with broad-spectrum disinfectant (e.g., Virkon). Vehicle sanitization is verified using an adenosine triphosphate (ATP) swab to detect residual ATP as an indicator of potential bacterial growth. All sanitations are documented on the vehicle log sheets.

Transports between VA and CCHMC are done in a personal vehicle with appropriate climate control. All animals are packed in filtered crates provided by commercial vendors.

g) Describe safety procedures for using medical gases and volatile anesthetics, including how waste anesthetic gases are scavenged.

Inhalational anesthesia machines are fitted with charcoal scavengers. The safe use time of the charcoal scavengers is determined by weight gained from use.

Precision vaporizer anesthesia machines are certified every other year and maintained by staff in between certifications. Each canister is weighed regularly (VMU machines and for PI-owned machines) and charcoal replaced according to manufacturer's recommendation. When using a drop box method for short term anesthetic delivery (e.g., euthanasia, tail clipping), the box must be used within the confines of a chemical fume hood.

IH&S periodically monitors each user with an isoflurane monitoring badge to ensure they are under the recommended exposure limits.

iii. Animal Experimentation Involving Hazards [*Guide*, pp. 20-21]

1) List, according to each of the categories noted below, hazardous or potentially hazardous agents currently approved to be used in animals that are or will be maintained for more than a few hours following exposure. If the hazardous agent cannot be listed by name for security/proprietary reasons, identify it by the general category of agent and level of hazard. *Note:* If preferred, this information may be provided in a Table or additional Appendix.

a) Biological agents, *noting hazard level* (CDC Biohazard Level, Directive 93/88 EEC, CDC or USDA/DHHS Select Agent, etc.). Examples may include bacteria, viruses, viral vectors, parasites, human-origin tissues, etc.

Hazard Agent	*ABSL*

Babesia microti	ABSL2
Babesia duncani	ABSL2
Human cancer cells and primary patient derived tumor tissue (e.g. prostate, renal cell carcinoma)	ABSL2 (inoculation/harvest)
Pneumocystis carinii	ABSL1
Antisense oligodeoxy-nucleotides	ABSL1

b) Chemical agents, *noting general category* of hazard (toxicant, toxin, irritant, carcinogen, etc.). Examples may include streptozotocin, BrdU, anti-neoplastic drugs, formalin, etc.

Chemical Agent	*Category*
Abiraterone	Teratogen
Bromodeoxyuridine	Mutagen, teratogen
Carbon tetrachloride	Carcinogen, heptatotoxin
Cisplatin	Acute toxin carcinogen
Concanavalin A	Hepatotoxin
Diethyl Ether	Flammable, irritant
Enzalutamide	Teratogen
Estradiol	Carcinogen, reproductive toxin
Ethynyl deoxyuridine	Mutagen, toxin
Formalin	Acute toxin, carcinogen
Ganciclovir	Mutagen, carcinogen, teratogen
Hydroxytamoxifen	Carcinogen
Isoflurane	Irritant, reproductive toxin,
Paraformaldehyde	Carcinogen, corrosive,
Testosterone	Carcinogen, teratogen
Tribromoethanol	Irritant

c) Physical agents (radiation, UV light, magnetic fields, lasers, noise, etc.).

UV Light 1000J/m^2

2) Experiment-Related Hazard Use [*Guide*, pp. 18-19; See also Chapters 2 and 3 in *Occupational Health and Safety in the Care and Use of Research Animals*, NRC 1997].
Note: Written policies and standard operating procedures (SOPs) governing experimentation with hazardous biological, chemical, and physical agents should be available during the site visit.

a) Describe the process used to identify and evaluate experimental hazards. Describe or identify the institutional entity(ies) responsible for ensuring appropriate safety review prior to study initiation.

All experimental hazards must be listed in the ACORP. Part of the ACORP protocol review and approval process involves a protocol safety assessment. The SRC/IBC review each ACORP prior to approval.

All potential chemical, biological and physical hazards are reviewed and if deemed hazardous and requiring special handling, a SOP is created for each hazard by PI/IH and attached to the ACORP when it is approved. The researchers and animal care staff must follow all safety precautions as set forth by the Safety Officers.

Only studies using ABSL-2 or lower can be performed at the CVAMC. The level of protection used is proportional to the agent being investigated. Any animal protocol involving hazardous agents is approved by the IACUC, and the information is passed on to the animal care staff to ensure proper handling of samples. We require an ABSL-2 SOP written by the PI and turned in with the ACORP and approved by the IACUC before any hazardous animal work can be done.

b) Describe how risks of these hazards are assessed and how procedures are developed to manage the risks. Identify the institutional entity(ies) responsible for reviewing and implementing appropriate safety or containment procedures.

Protocol specific training is provided as outlined in the pre-review application. Scientific Research Safety forms are required for all protocols.

Each lab using hazardous agents in their protocols are required to have agent specific SOP's in place outlining the agent background, transmissibility, route of infection, etc. prior to the ACORP being approved. These SOP's, once approved by the IACUC, are reviewed with the VMU staff and posted in the room. This ensures that anyone coming in contact with hazardous animals knows that special handling is required and is prepared to follow proper personal protective equipment (PPE) requirements as well as waste handling procedures.

Final approval and oversite of the practices and procedures involved in husbandry and managing risks of use of hazards with the animals requires the approval of the AV, the appropriate safety officer, and the SRS/IBC, by determining proper containment procedures.

c) Describe the handling, storage, method and frequency of disposal, and final disposal location for hazardous wastes, including infectious, toxic, radioactive carcasses, bedding, cages, medical sharps, and glass.

If an ABSL-2 hazardous agent is used in animals, all bedding is changed and bagged in a biosafety cabinet (BSC) in the study room. The cages and bedding are then autoclaved before going to the rack washer. We have an SOP in place detailing the handling of ABSL-2 caging, bedding and animals. In addition, for all protocols that use ABSL-2 agents, there is a SOP #25 required as part of the ACORP submission packet, for the safe handling of animals and bedding associated to that specific agent and protocol. These SOP's are then posted in the ABSL-2 room for reference by the animal technicians.

Husbandry practices and other animal related procedures for each protocol using hazardous agents are developed by the principal investigator in consultation with the AV and an appropriate safety officer. Final approval of the practices and procedures involved in husbandry of the animals requires the approval of the attending veterinarian, the appropriate safety officer, and SRS/IBC. Oversight is provided by IH&S either through the BSO or the Radiation Safety Officer.

Our ABSL-2 work is in dedicated space in VMU (b)(6) All work is conducted in a class II-A2 biosafety cabinet (BSC). Disposable gown, face mask, hair bonnet and disposable gloves are required for handling. SOP's are in place for handling all hazardous materials. Animals with biohazardous agents are housed in PIV cages with HEPA filtered exhaust air.

Carcasses are placed in the carcass freezer in a locked box until they are transferred to the biohazard room of the hospital for pick up by a contracted waste company. All bedding is changed and bagged in a class II-A2 biological safety cabinet in the study room. Disinfection of cages and contents after use is achieved by autoclaving at 121 ° C for 40 minutes. Bedding and food is discarded and cages are then sanitized in the cage washer. Necropsy procedures are conducted in the biosafety cabinet to minimize personnel exposure to potential infectious agents.

When a hazardous agent is used all bedding is changed and bagged in a class II-A2 BSC in the study room. The cages are autoclaved before going through the rack washer.

Sharps containers are collected when full. All biohazardous material is placed in a room labeled "Bio-Hazard Material", located by the dumpster until incinerated by a private contractor. Glass is collected in puncture proof boxes, sealed up and discarded in the dumpster.

(See SOP VMU 025 – ABSL-2 Husbandry for Animal Studies, available upon request)

Sharps containers are collected when ¾ full. All biohazardous material is placed in a room labeled “Bio-Hazard Material”, located by the dumpster until incinerated by a private contractor. Glass is collected in puncture proof boxes, sealed up and discarded in the dumpster.

d) Describe aspects of the medical evaluation and preventive health program specifically for personnel potentially exposed to hazardous agents.

Only trained personnel will be allowed to work with hazardous substances. The Safety Protocol, Material Safety Data Sheets (MSDS), biosafety and general safety procedures will be reviewed and approved prior to the use of any hazardous biological or chemicals. When appropriate, vaccination or other preventative health measures will be used in concordance with the personnel health physician’s recommendation. All contact with hazardous substances is reported to the RSO through the Employee Health Office.

3) Hazardous Agent Training for Personnel [*Guide*, p. 20]

Describe special qualifications and training of staff involved with the use of hazardous agents in animals.

Protocol specific training is provided as outlined in the pre-review application. Scientific Research Safety forms are required for all protocols.

Each lab using hazardous agents in their protocols are required to have agent specific SOP’s in place outlining the agent background, transmissibility, route of infection, etc. prior to the ACORP being approved. These SOP’s, once approved by the IACUC, are reviewed with the VMU staff and posted in the room. This ensures that anyone coming in contact with hazardous animals knows that special handling is required and is prepared to follow proper PPE requirements as well as waste handling procedures.

4) Facilities, Equipment and Monitoring [*Guide*, pp. 19-20]

a) Describe locations, rooms, or facilities used to house animals exposed to hazardous agents. Identify each facility according to the hazard(s) and containment levels (if appropriate).
Note: If preferred, information may be provided in a Table or additional Appendix.

We currently have one room designated for ABSL-2 animal studies, (b)(6)

(b)(6)

b) Describe circumstances and conditions where animals are housed in rooms outside of dedicated containment facilities (i.e., in standard animal holding rooms). Include practices and procedures used to ensure hazard containment.

Animals administered a hazardous agent are not housed in rooms outside of dedicated containment facilities.

For studies where human tumor xenografts are used, mice are housed in standard holding rooms because mice are only considered ABSL-2 when performing the injections and when harvesting tissues or conducting necropsy. All procedures with animals and cells will be conducted in the Class II-A2 BSC. During injections, a sign will be placed on the door of the room notifying others that ABSL-2 procedures are taking place and what precautions to take. After cell injection procedures, all lab coats worn must be autoclaved prior to washing. The coats are bagged in an autoclavable biohazard bag and sent through the autoclave, then added to the regular laundry. The BSC is wiped down with disinfectant and excess biological materials are disposed of in the bio-hazardous waste container.

Once injections are complete and room cleaned up, no one should enter the room until the following day, when the sign can be taken down. Following tumor cell inoculation into the mice, cages are not to be changed for 3 days to avoid any potential risks to staff. After the 3 days, normal husbandry practices are used. All cages are changed and animals handled within the BSC. Cages with animals carrying human or murine cell lines will be labeled as such. Animal carcasses must be red bagged and placed in the ABSL-2 lockbox located in the carcass freezer for disposal.

c) Describe special equipment related to hazard containment; include methods, frequency, and entity(ies) responsible for assessing proper function of such equipment.

Currently we have one animal room, approximately 200 sq. feet in which the infected, ABSL-2 level animals can be housed. All infection handling is done in that room including euthanasia (a CO2 tank is available) of infected animals. All work is done in a Class II-A2 BSC and clidox (Chlorine dioxide solution) is used for surface decontamination prior to items being removed from the room. The animals are housed in individually ventilated cages (PIV) with a HEPA filter for supply and exhaust air circulation. The room has negative air balancing to the hallway. The BSC is certified once a year to confirm proper function. If animal techs see any alarms or maintenance lights on the BSC or PIV housing rack, those are addressed prior to resuming cage changing.

Chemical Fume Hoods – Certified annually by Micro Clean; Fume hood in (b)(6) will alarm if not functioning within set parameters.

d) Describe the husbandry practices in place to ensure personnel safety, including any additional personnel protective equipment used when work assignment involves hazardous agents.

Biocontainment – for ABSL-1/ABSL-2 – rooms containing biohazards have appropriate signage posted on the entrance door to the room. Signage includes: biohazard symbol, agent(s) in use, required PPE, and emergency contact information. Studies are conducted in dedicated negative pressure 100% exhaust rooms using static microisolator cages and a BSC. Disinfectants approved by the SRS/IBC are utilized for surface disinfection (e.g., clidox). Cages are individually identified with "Biological Hazard" labels affixed to the cage card with the following information documented: agent, date of agent inoculation, administration route, and researcher's initials. All cages are handled and changed within a BSC. VMU staff and research personnel wear the following PPE: disposable gown, Tyvek sleeves, hair bonnet, shoe covers, double gloves, and surgical face mask or N95 respirator whenever necessary. All cages are dumped within the BSC into a biohazard bag. The cages are sprayed with a disinfectant approved by the SRS/IBC prior to being bagged and transported to dirty side cage wash. All biological waste (bedding, feed, carcasses) is appropriately disposed of by VMU staff by taking prepared waste and carcasses to the Biohazard pick up room at the main dock, where waste is picked up by a 3rd party vendor, contracted by the hospital.

Handling Chemicals:

General guidelines for handling chemicals:

1. Store chemicals in a cool, central area.
2. Store volatile chemicals in a special cabinet and prevent vapors from collecting and creating a hazard.
3. Dispense cleaning chemicals to people who have been instructed in their use.
4. Follow instructions on the label. Higher use levels are rarely more effective and will probably be hazardous.
5. NEVER use the contents of an unlabeled container. Do not assume you know what is in the container - it is cheaper to waste the contents than to make a mistake.
6. NEVER mix different chemicals unless the manufacturer or a knowledgeable person authorizes you to do so: Combinations can be ineffective or hazardous. Combining bleach and ammonia, for example, creates noxious fumes.

7. DO NOT REUSE empty containers for a different product. Rinse the container and discard it properly.

If chemicals are purchased in bulk containers and must be dispensed into smaller quantities, dispense the chemicals into smaller containers of the same quality as the original containers and that have not been used for storage of another product. All such containers should be labeled permanently. Scavenging and ventilation systems must be used for reduction of waste anesthetic gases.

Specific guidelines for handling chemicals.

1. Paraformaldehyde/Formaldehyde:
   This chemical can be used in accordance with fumigation guidelines to fumigate rooms in which infectious agents have been used as well as used as a tissue fixative when harvesting tissue samples. Paraformaldehyde and the gas formaldehyde that is produced on heating are very irritating to the eyes, skin, and respiratory tract. Formaldehyde under some circumstances is a carcinogen. Protective disposable gloves face mask, and lab coat should be worn when handling paraformaldehyde. Protective disposable gloves, coveralls, head cover, boots, and a gas mask must be worn if it becomes necessary to enter a room containing formaldehyde vapors in the case of fumigation.

2. Other disinfectants, acids, cleansers, and all parasiticides are potentially toxic and irritating to the eyes, nose, and skin. Special precautions must be used when handling the concentrates of these agents. In any case, gloves must be worn if there is potential for contact with the hands. Goggles must be worn if you are doing a procedure where there is potential for splashing the material into your eyes, and a face mask should be worn if you are doing a procedure that produces significant aerosol, such as doing a necropsy or disinfecting a room with the power washer. A lab coat or protective rubber apron must be worn if you are doing a procedure that would wet your regular working clothing. If eyes or skin are contaminated, they should be flushed with large amounts of running water. If clothing becomes contaminated with these agents, clothing should be removed and washed before wear.

Experimental chemicals

1. Some chemicals used experimentally in animals have carcinogenic, mutagenic, or teratogenic potential in humans. Special precautions must be taken when working with these chemicals.
2. Warning signs must be posted naming the chemical and stating its danger.
3. Animals injected with or fed such chemicals must be housed in an area separate from other animals.
4. Use disposable cages to house contaminated animals. If this is not possible, do not mix reusable cages used for these animals with those

from other toxicity studies or with equipment used with the general animal population. Personnel handling these cages should wear gloves at all times.

5. Bedding changes must be done under a hood.
6. Personnel caring for these animals must wear disposable gloves, head covers, face masks, foot covers, and coveralls when working in the area.
7. These clothing items must not be taken from the local work area. Disposable clothing and disposable equipment must be discarded into covered containers lined with plastic bags. Bags should be labeled with investigator's name, telephone number, and chemical used. This waste should be disposed of by incineration.
8. Animal carcasses, bedding, and waste should be bagged, labeled as above, and disposed of by incineration.

e) Incidental Animal Contact and Patient Areas

i) List and describe facilities that may be used for both animal- and human-based research or patient areas, including the policies and procedures for human patient protection, facility decontamination, animal transport through common corridors or elevators, and other personnel protection procedures.

None

ii) Describe any *other* circumstances in which animals or caging equipment are transported in common use corridors or elevators (e.g., have the potential to come in contact with individuals not associated with the animal care and use program), and measures taken to mitigate risks associated with such use.

Any animals that are transported outside of the VMU, such as rodents going to approved labs for surgery, testing or tissue harvest are transported within a secondary (non-transparent) container with a lid so not to expose individuals not associated with the animal care and use program to allergens or any other potential hazard.

Rodents are transported in clean static microisolator caging or filtered shipping containers and covered with a breathable opaque material to contain allergens and prevent public viewing. All cages (or shipping containers) must have a cage card and cage lids must be secured to the cages with a clip, tie, or residue-free tape to prevent escape of the animals.

The only elevator that is used for this purpose is the (b)(6) elevator and corridors connecting research service space.

For further information please see section II.E, pg. 61 in the "Cincinnati

VA Medical Center Animal Care and Use Program Policy, Guidelines and Procedures".

B. Program Oversight

1. The Role of the IACUC/OB [*Guide*, pp. 24-40]

a. IACUC/OB Composition and Function [*Guide*, pp. 17; 24-25]

Please provide a Committee roster, indicating names, degrees, membership role, and affiliation (e.g., Department/Division) as **Appendix 7**.

i. Describe Committee membership appointment procedures.

IACUC Chair in consultation with the R&DC forwards the names of nominees for the IACUC to the MCD/IO. The MCD/IO officially appoints members in writing, including the specific length of the appointment. The Chair of the IACUC is appointed annually without a lapse in service with no limit of reappointment times. Members other than those who are designated ex officio (appointed on the basis of their position, such as the institutional veterinarian) may serve terms of up to 3 years and may be re-appointed without lapse in service to the IACUC. An IACUC member should be appointed to the R&DC, and the VMO/VMC or another member of the IACUC should be appointed to the SRS/IBC. The IACUC must be composed of sufficient members to conduct the activities discussed in its mission, and must include at a minimum:

1. Scientists who represent the wide diversity of activities of animals used at the CVAMC
2. Veterinarian with programmatic responsibilities (VMO/VMC)
3. Community Representative
4. Non-scientific representative
5. At least one IACUC member who is a member of the R&DC

- **Chair:** cannot simultaneously chair another subcommittee. The Chair needs to be a more senior scientist with animal research experience and good committee management skills. The Chair is a voting member of the committee.

- **Vice-Chair (Alternate Chair):** is to be chosen from membership.

- **Members:** A minimum of five members are required to serve as voting members to constitute an IACUC. Only a properly constituted IACUC may conduct official business.

    - Four voting members who are practicing biomedical scientists experienced in research involving animals (one being the Veterinarian).

    - One voting member who represents community interests and is not affiliated with the CVAMC, and who is not part of the immediate family of a person who is affiliated with the medical center (non-affiliate or community member).

  - One voting lay member who is not involved in animal research (non-scientist or lay member).

- **Alternate Members**: Individuals with expertise in clinical or basic research will be appointed as alternate members of the Committee. These people will be available to serve in place of regular members when they cannot attend a meeting.

- **Ex-Officio Members:**

  - The VMO/VMC who serves as a voting member.
  - At least one member of the Animal Research Facility and preferably the Managing Director of the VMU, serves as a voting member.
  - The ACOS/R with non-voting status.
  - The Administrative Officer for Research serves with a non-voting status.
  - The RCO serves with a non-voting status.

See Appendix 7 for IACUC Membership Roster

ii. Describe frequency of Committee meetings. Note that **Appendix 8** should contain the last two IACUC/OB meeting minutes.

The full IACUC membership meets not less than 11 times per year, on the 3rd Tuesday of the month at 1:30 p.m. unless notified otherwise, with additional meetings called by the Chair as deemed necessary.

iii. Describe the orientation, training, and continuing education opportunities for IACUC/OB members. [*Guide*, p. 17]

Newly appointed IACUC members must complete introductory training, for example, https://www.citiprogram.org as well as access to the "Institutional Animal Care and Use Committee Guidebook" and "*The Guide for the care and use of Laboratory Animals*"

Continuing education: IACUC members are encouraged to attend conferences where topics specific to IACUC issues are presented. Published articles or presentations from the central office of particular interest to the IACUC oversight process are included in the IACUC monthly meeting agenda.

b. Protocol Review [*Guide*, pp. 25-27]

A blank copy of your institution's protocol review form should be provided as

Appendix 9. Also include forms used for annual renewal, modifications, amendments, etc., as applicable.

i. Describe the process for reviewing and approving animal use. Include descriptions of how:

- the IACUC/OB weighs the potential adverse effects of the study against the potential benefits that may result from the use ("harm-benefit analysis"),
- protocols that have the potential to cause pain or distress to animals are reviewed and alternative methodologies reviewed,
- veterinary input is provided, and
- the use of animals and experimental group sizes are justified.

Note: Make sure you address each of the items above.

The IACUC reviews and approves all research proposals involving the use of animals, regardless of source of funding, in accordance with the *Guide for the Care and Use of Laboratory Animals* and the Animal Welfare Act. All research protocols (including preliminary or pilot studies) are also reviewed for scientific justification and approved by R&D Committee. Protocols are reviewed annually using the Annual Protocol Progress Report form provided by the research office. The IACUC reviews all animal use protocols regardless of funding and reviews any significant changes to approved protocols. Preliminary review of protocols is initially performed by the VMC. There are times when a one-on-one meeting is conducted to facilitate the veterinary pre-review process. Correspondence continues through e-mails until all suggested changes have been addressed. Upon completion of veterinary review approval, the protocol is submitted to the IACUC member review. Two committee members are assigned as primary reviewers to provide further feedback at the convened IACUC meeting. The IACUC then conducts full committee review of proposed research through the convened meetings at which a quorum (a majority of voting members) is in attendance physically or via speaker phone. Protocol action includes: approval, vote to DMR, require modification to secure approval by FCR, or withhold approval.
All research protocols (including preliminary or pilot studies) are also reviewed for scientific justification and approved by R&D Committee. Progress of ACORPs are reviewed annually using the Annual Protocol Progress Report form provided by the research office. Safety officers (BSO, IH&S, RSO) review each ACORP for hazards and ensure SRS/IBC committee approval has been secured and safety practices established prior to final ACORP approval.

1. Approved: The Administrative Assistant will inform the PI of IACUC actions. The investigator will be sent an approval notice from the IACUC indicating that no work can begin on the ACORP until the investigator has received written approval from the R&DC and the SRS/IBC. Approval of the ACORP is the date of approval of the protocol by a convened IACUC meeting or the

Designated Member Review (DMR) if this was the method approved by the convened IACUC.

2. Modifications Required to Secure IACUC Approval - will include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

   When substantive information is lacking from a protocol, the committee may have questions requiring a response from the PI. In such situations, the IACUC may take the following actions:
   a) If quorum of the IACUC are present at a meeting, the committee may vote to require modifications to secure approval and have the revised research protocol reviewed and approved by DMR, or returned for full committee review (FCR) at a convened meeting.
   b) If quorum of the IACUC are not present at a meeting, the committee may use DMR subsequent to FCR according to the following stipulations:
   * All IACUC members have agreed in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.
   * In order to conduct reviews by DMR subsequent to FCR, the institution should specify its intention to conduct reviews in this manner in its Assurance with OLAW.

3. Disapproved: The investigator will be sent a letter describing the reasons for disapproval. Disapproval of the protocol usually occurs when the IACUC determines that the risk of the procedures outweigh any benefit to be gained. The investigator may discuss the review with the Chairperson and/or submit a revised protocol that has been signed by the VMO for re-review by the full IACUC.

The IACUC conducts a thorough review of a proposed ACORP to evaluate how the study will serve the good of society so that the benefits outweigh the pain or distress that may be caused in the animals used in the protocol. The IACUC ensures that the proposed study would use methods that would minimize the pain and distress to the animals. In their review, the IACUC evaluates the thoroughness of the alterative methodologies to evaluate whether an investigator has effectively sought for replacement methods that would not involve the use of live animals. The IACUC evaluates the justification for group sizes by ensuring that the smallest number of animals would be used to achieve the study objective. The veterinarian and VMU Managing Director both actively participate in the FCR, and provide valuable input on procedures may cause pain or distress in the animals, and on the resources needed to provide appropriate husbandry for the animals. For new procedures that have the potential to produce physiological impairment with subsequent pain and/or distress, the IACUC may elect to approve a small number of the total animals requested and require the PI and/or VMU Managing Director/VMC to report back to the IACUC before additional animals will be approved.

Once a protocol with painful and/or distressful procedures is approved, they are monitored by: observation by VMU staff, post-approval monitoring (PAM), semiannual inspections, and veterinary oversight. If the IACUC determines that the experiments to be performed warrant additional oversight, they may require VMC or VMU Managing Director to be present.

Justification for animal and experimental group sizes: When submitting a ACORP for IACUC review, PIs are required to justify and account for the number of animals required. This generally involves listing the number of animals per experimental group and the variables that constitute each study (e.g., age, genotypes, sex, time points, and treatments). PIs are required to justify group size either based on a power analysis, cited publication, quantity of tissue required, and/or need for a pilot study. The animal numbers and justification are reviewed by the IACUC prior to approval.

See Appendix 9, for related forms

ii. Describe the process for reviewing and approving amendments, modifications, and revised protocols. If applicable, include a description/definition of "major" vs. "minor" amendments.
Note: If preferred, this information may be provided in a Table or additional Appendix.

All requests for changes must receive IACUC approval prior to implementation, via a fully convened IACUC meeting. All IACUC members shall receive a description of such modifications by, as part of their monthly committee packet. All changes or amendments in protocols involving radioisotopes/physical/ biological/chemical hazards must also be submitted in writing by the investigator to SRS/IBC, in addition to the IACUC. Final ACORP approval will not be given until approval is received from SRS and R&D. Modifications are reviewed following the same outcomes as outlined in the previous section are used.

The IACUC recognizes that requiring all modifications to existing protocols exclusively by FCR could potentially reduce the flexibility of the protocol review process and increase the time to protocol approval. We understand that DMR and administrative approval processes are an option; however, we as a committee have determined that if emergency modification situations should arise, we would call for a secondary convened meeting to address and vote on the request.

c. Special Considerations for IACUC/OB Review [*Guide*, pp. 5; 27-33]

i. Experimental and Humane Endpoints [*Guide*, pp. 27-28]

1) Describe the IACUC/OB's review of "humane endpoints," i.e., alternatives to experimental endpoints to prevent or in response to unrelieved animal pain and distress.

Humane endpoints are examined on a case by case/per protocol basis. Endpoints are established in conjunction between the principal investigator, veterinarian, and IACUC. Endpoints are developed in the protocol. If after approval the endpoints require refinement an amendment to the protocol is submitted for approval.

2) For studies in which humane alternative endpoints are not available, describe the IACUC/OB's consideration of animal monitoring and other means used to minimize pain and distress (e.g., pilot studies, special monitoring, other alternatives).

In situations where humane alternative endpoints are not available or established, enhanced observational assessments by research and/or VMU staff may be mandated by the IACUC and described in the protocol. The monitoring cards are placed on each cage. The cards are utilized as a monitoring and communication tool between the researchers and VMU staff. The researchers document their individual animal assessment on the cage card, which is reviewed by VMU staff. Animals are tracked until their experimental endpoint is reached. In some situations where endpoints may be difficult to determine, the IACUC may mandate a pilot study or veterinary oversight of the proposed procedure. The researcher and VMC/VMU Managing Director report the findings of pilot studies to the IACUC for consideration prior to securing approval for a full-scale study.

3) Identify personnel responsible for monitoring animals for potential pain and distress and describe any mechanisms in place to ensure that the personnel have received appropriate species- and study-specific training.

Principal investigators are responsible for ensuring that their research team is appropriately qualified and trained in protocol specific procedures, including expected clinical symptoms and humane endpoints. VMU staff are also trained to recognize clinical signs, as well as reporting procedures for notifying the appropriate personnel.

ii. Unexpected Outcomes that Affect Animal Well-being [*Guide*, pp. 28-29]

Describe how unexpected outcomes of experimental procedures (e.g., unexpected morbidity or mortality, unanticipated phenotypes in genetically-modified animals) are identified, interpreted, and reported to the IACUC/OB.

Unexpected outcomes are identified, interpreted and reported to the IACUC by the PI and/or the veterinary staff. Decisions as to the appropriate response to the unforeseen event are the responsibility of all three entities. When an unexpected outcome is identified, VMO or VMU Managing Director works with the researchers to: (1) minimize pain and distress through treatment or euthanasia, (2) identify the cause, (3) determine if additional training is required, and (4) determine if the endpoint criteria and/or pain class in the ACORP needs to be updated. Unexpected outcomes are presented to the IACUC by the VMO or VMU Managing Director at convened meetings.

iii. Physical Restraint [*Guide*, pp. 29-30]

Note: This section is to include only those protocols that require prolonged restraint. Brief restraint for the purpose of performing routine clinical or experimental procedures need not be described.

1) Briefly describe the policies for the use of physical restraint procedures or devices. Include, if applicable, the IACUC/OB definition of "prolonged."

Prolonged restraint (usually an hour or longer) should be avoided unless it is essential for achieving research objectives.

The overall policy of the Committee is that no long-term physical restraint of animals is permitted without scientific justification. Committee approval requires a strong scientific justification including documentation of the duration, nature of the restraint, total number of restraints and intervals between restraints.

The Committee inspects experimental procedures utilizing physical restraint during facility site inspections.

2) Describe animal restraint devices that are used or have been used within the last three years. For each device, briefly describe

- the duration of confinement
- acclimation procedures
- monitoring procedures
- criteria for removing animals that do not adapt or acclimate, and
- provision of veterinary care for animals with adverse clinical consequences.

Note: If preferred, this information may be provided in a Table or additional Appendix.

We have two studies with an approved prolonged physical restraint as a means to induce stress in experimental animals. These studies are scientifically justified as a protocol to induce PTSD like trauma. Animals will be placed in plastic restraint devices for up to 2 hours. Restraint devices are commercial plexiglass restrainers, 21 cm in length with a 5-cm opening, equipped with ventilation holes. Rats will be monitored at regular 15-minute intervals; however, the goal is to induce stress so stress will not be relieved.

We also utilize momentary restraint devices used for tail vein injections and other injections as well and a restraint cup for tattooing tails. These devices are only used on an as needed basis and are only used briefly to accomplish the injection or tattoo.

iv. Multiple Survival Surgical Procedures [*Guide*, p. 30]

Note: One survival surgical procedure followed by a non-survival procedure is not included in this category.

1) Describe the IACUC/OB's expectations regarding multiple survival surgery (major or minor) on a single animal.

Multiple major survival surgeries on a single animal are discouraged, but may be permitted if both are scientifically justified by the applicant and approved by the IACUC.

1. Examples of Justifications
   - Surgeries are interrelated components of one project
   - If this action conserves scarce animal resources
   - If there are clinical reasons for multiple surgeries (animal health related as opposed to research).
   - Cost savings is not a scientific justification.
2. Approved ACORPs for major multiple surgeries are scrutinized carefully by the veterinary staff and the IACUC, with particular attention to post-operative care and record keeping throughout the duration of the study.
3. The IACUC may request progress reports from the PI and/or the veterinary staff to assess the health and well-being of animals on the ACORP.

2) Summarize the types of protocols currently approved that involve multiple major survival surgical procedures

Note: If preferred, this information may be provided in a Table or additional Appendix.

None

v. Food and Fluid Regulation [*Guide*, pp. 30-31]. *Note:* This does not include pre-surgical fast.

Summarize the types of protocols that require food and/or fluid regulation or restriction, including:

- justification
- species involved
- length and type of food/fluid regulation
- animal health monitoring procedures and frequency (e.g., body weight, blood urea nitrogen, urine/fecal output, food/fluid consumption)
- methods of ensuring adequate nutrition and hydration during the regulated period

Note: If preferred, this information may be provided in a Table or additional Appendix.

Food and/or fluid regulation must be scientifically justified and approved by the IACUC. We have an ACORP for fluid regulation for up to 24 hours to determine the effect of water deprivation on kidney concentrating ability and kidney function in mice lacking one or more kidney electrolyte transporters to mimic the effect of desert conditions, which are encountered by soldiers during training or in battles. Mice will be observed and weighed daily. If more than 20% loss of body weight is observed, the mouse will be removed from the study and euthanized. Mice may or may not be placed in metabolic cages during this procedure. Urine from mice placed in metabolic cages will be measured for urine osmolality. Mice usually have an average urine osmolality of 2,500 mOsm. If the desired effect on kidney function (urine osmolality) in mice (4,000 mOsm) is observed at a time point earlier than 24 hours, the experiments will be terminated (Protocol #17-06-24-01 "Identification and Characterization of Chloride/Bicarbonate Exchangers in Epithelial Tissues").

Health Monitoring: Experimental procedures utilizing food or water restriction must include a program for monitoring of physiologic and behavioral indexes. When food or water deprivation is being conducted, a log sheet is maintained, and kept with the animals, with the following information:

1. Record of food/water schedule
2. Health status of the animals, including weight
3. Any adverse events
4. Criteria (such as weight loss or state of hydration) for temporary or permanent removal of an animal from the experimental protocol must be defined

Ensuing adequate nutrition:

1. Restriction for research purposes must be scientifically justified and approved by the IACUC.
2. The least restriction that will achieve the scientific objective should be used. In the case of conditioned-response research protocols, use of a highly

preferred food or fluid as positive reinforcement, instead of restriction, is recommended.

3. When experimental situations require food or fluid restriction, at least minimal quantities of food and fluid must be available to provide for development of young animals and to maintain long-term well-being of all animals.
4. When only fluid restriction is used, special attention must be given to ensure that animals consume a suitably balanced diet because food consumption might decrease with fluid restriction.

vi. Use of Non-Pharmaceutical-Grade Drugs and Other Substances [*Guide*, p. 31]

Describe the IACUC/OB's expectations regarding the justification for using non-pharmaceutical-grade drugs or other substances, if applicable.

The use of non-pharmaceutical grade chemical compounds in experimental animals under certain circumstances has been, and will continue to be, a necessary and acceptable component of biomedical research. Their use should be based on:

1. Scientific necessity
2. Non-availability of an acceptable veterinary or human pharmaceutical grade product
3. Incorrect formulation (e.g., presence of additives that could negatively impact the research, improper concentration, improper form [e.g., tablet, capsule]
4. Specific review and approval by the IACUC

In preparing and reviewing proposals to use non-pharmaceutical grade products, investigators and IACUCs consider a number of related animal welfare and scientific factors including safety, efficacy, and the inadvertent introduction of research complicating variables. While issues such as sterility, pyrogenicity, stability, pharmacokinetics and quality control are assumed to have been addressed during the course of producing pharmaceutical grade drugs, the same cannot always be said for substances produced in the research laboratory using non-pharmaceutical grade chemical compounds (e.g. saline, glucose, etc.). Cost savings alone is not an adequate justification for using non-pharmaceutical compounds in animals (e.g. Halothane, etc.).

Although the potential animal welfare consequences of complications are less evident in non-survival studies, the scientific issues remain the same. The principles and need for professional judgment outlined above still apply.

The use of non-pharmaceutical grade drugs in vertebrate species must be explicitly detailed in the ACORP and IACUC approval gained prior to use of the drug.

Reconstituted drug (vial) label must include the date of reconstitution in order to assure timely disposal of the drug.

vii. Field Investigations [*Guide*, p. 32]
Describe any additional considerations used by the IACUC/OB when reviewing field investigations of animals (non-domesticated vertebrate species), if applicable.

Not Applicable

viii. Animal Reuse [*Guide*, p. 5]

1) Describe institutional policies regarding, and oversight of, animal reuse (i.e., on multiple teaching or research protocols).

We currently do not have protocols that involve the reuse of animals on multiple protocols.

2) Briefly describe the types of activities currently approved that involve the reuse of individual animals.
Note: A list of specific protocols involving reuse of animals should be available during the site visit.

We have no currently approved protocols that involve the reuse of animals.

3) Describe other instances where the final disposition of animals following study does not involve euthanasia, including adoption, re-homing, rehabilitation, etc.
Note: A list of specific protocols involving reuse of animals should be available during the site visit.

We do not have a re-homing or adoption policy.

2. Post-Approval Monitoring [*Guide*, pp. 33-34]

a. Describe mechanisms for IACUC/OB review of ongoing studies and periodic proposal/protocol reviews (e.g., annual, biennial, triennial, or other frequency).

Annual review - Policy requires that all research involving the care and use of vertebrate animals be reviewed at least every year from the date of Committee approval as long as the study continues. A request for re-approval form is sent to each PI approximately eight weeks prior to the required re-approval date. The PI is responsible for making sure the annual progress report form and any updates to the ACORP specific SOP is completed and returned to the Administrative Assistant. Yearly review and approval is performed at a convened IACUC meeting. The completion of annual training is necessary for the yearly re-approval from the IACUC. The Committee approval for a specific protocol, with an annual re-approval for each intervening year, will be for a 3-year period only. In the event of failure to receive full approval of the re-approval by the anniversary date, the animals will be transferred to the VMU holding protocol at which time no animal research can be conducted.

3 Year renewals - Each Animal-use protocol shall be unique and shall be active for a maximum period of three (3) years. At the end of this three-year period, it shall be automatically inactivated and all animal activities covered under it shall be considered complete.

Ongoing or additional animal activities as may be required by the specific protocol must be submitted as a new animal use protocol which will be assigned a new number and reviewed by the IACUC. The Administrative Assistant will notify the investigator in writing when three-year approval will expire. Notification will be approximately five months prior to the expiration date in order to assure enough time for the newly written protocol to be reviewed in a timely fashion.

In addition, the Managing Director of the VMU and the VMC monitor research procedures as they are conducted to ensure the use of animals is in accord with the *Guide*. In addition, the Managing Director has instructed and trained the Animal Husbandry Staff to perform morning and evening animal checks and she provides periodic physical examinations of animals prior to and during study. The investigators themselves, who have substantial investments in the quality of animal care, also frequently provide incisive surveillance of the quality of animal care.

b. Describe the process and frequency with which the IACUC/OB reviews the program of animal care and use.

IACUC Semiannual Inspections: The IACUC conducts semi-annual reviews of the animal program and animal facilities at least once every 6 months including review of affiliate laboratory sites according to signed memoranda of understanding and partial off-site agreements. At least three IACUC members (two voting members) will perform the inspections.

The IACUC procedures for conducting semiannual program reviews are as follows: The Committee Administrator forwards all VA IACUC members the Semi-Annual Review Checklist (including program review and facility inspection review) with the Committee agenda at least one week prior to the scheduled meeting during the months of January and July. During the convened IACUC meeting the program review is discussed point by point agreed upon and documented. Final approval of the completed Semi-Annual Review checklist is documented by committee member signature post facility inspection and discussion of all points at the next month's convened meeting. The CVAMC recognizes that OLAW provides a Facility Review Checklist, however, per VA policy; we utilize the official VA Semiannual Evaluation of the Institutional Animal Care and Use Program and Facilities checklist in its newest version.

During the conduct of semi-annual evaluations, the IACUC: (1) Distinguishes significant program deficiencies from minor deficiencies; (2) Develops a specific plan for the correction of all program and facility-related deficiencies that includes projected dates for correction; (3) Identifies IACUC-approved departures from the AWAR, *Guide*, or PHS Policy, and provides justification for the departure(s); and (4) Includes minority opinions and views expressed by IACUC members.

Once both the program review and the animal facility inspection are finalized and the final report is voted on and signed, the reports are presented to the IO. VA regulations stipulate that the report must be presented to the IO by the VMO/VMC, IACUC Chair and the ACOS/R in a real-time meeting within days. The final report with all signatures must then be send to the Chief Veterinary Medical Office within 60 days of completion by the IACUC.

c. Describe the process and frequency with which the IACUC/OB conducts facility and laboratory inspections.

- Describe the rationale or criteria used for exempting or varying the frequency of reviewing satellite holding facilities and/or animal use areas.
- If contract facilities or contractor-provided personnel are used, describe procedures used by the IACUC/OB to review such programs and facilities.

Note: A copy of the last report of these reviews should be included as **Appendix 10**.

It is the responsibility of IACUC to inspect, at least semi-annually, the VMU animal facilities, individual laboratories, and study areas. At least 2 IACUC voting members shall perform the inspections. The VA Semiannual Evaluation of the Institutional Animal Care and Use Program and Facilities form, is utilized as the inspection is conducted. The Inspection of the Facilities focuses on a physical and visual evaluation of buildings, equipment, and the environment in which animals are maintained and utilized. During the conduct of semi-annual evaluations, the IACUC: (1) Distinguishes significant program deficiencies from minor deficiencies; (2) Develops a specific plan for the correction of all program and facility-related deficiencies that includes projected dates for correction; (3) Identifies IACUC-approved departures from the AWAR, *Guide*, or PHS Policy, and provides justification for the departure(s); and (4) Includes minority opinions and views expressed by IACUC members.
The report must then receive approval by a majority vote of the IACUC at a convened meeting. Letters will be sent by the Research Service administration on behalf of IACUC to the responsible parties (e.g. investigator, Department Chair, facilities management, physical plant office or Associate Chief of Research) informing them of the deficiencies and a response time. Facility deficiencies are sent to the facilities manager and the Institutional Official. Conditions, which seriously impact health and well-being of animals observed by the Subcommittee of the IACUC, will be reported immediately to the IACUC Chair for immediate action. All areas where animals are used are inspected during every inspection.

The VA IACUC relies on inspections performed at CCHMC and the UC by their respective IACUC's as oversight of those facilities. Our IACUC receives the other institution's reports semi-annually once they are finalized and signed off by their IO.

Refer to Appendix 10 for a copy of the last IACUC program review and semiannual facilities inspection reports.

d. If applicable, summarize deficiencies noted during external regulatory inspections within the past three years (e.g., funding agencies, government, or other regulatory agencies) and describe institutional responses to those deficiencies. *Note:* Copies of all such inspection reports (if available) should be available for review by the site visitors.

Regulatory inspections include VA Office of Research Oversight (ORO) and AAALAC. The VA has fully addressed all actions requested by AAALAC in 2016.

e. Describe any other monitoring mechanisms or procedures used to facilitate ongoing protocol assessment and compliance, if applicable.

As part of the VA Program review, the IACUC must randomly review IACUC records representing at least 5 percent of the total active projects (a minimum of five). The purpose of the review is to determine if appropriate documentation of initial review, approval letter(s), annual and triennial approvals, modifications, and investigator correspondence are present. This review is performed annually at a fully convened meeting. On a routine basis the Managing Director is in the facility overseeing the daily ongoing activities and can bring up any issues that are noted at the IACUC meetings.

3. Investigating and Reporting Animal Welfare Concerns [*Guide*, pp. 23-24]

Describe institutional methods for reporting and investigating animal welfare concerns.

Deficiencies (or apparent non-compliance) in animal care, use, or treatment are reported to the VMO/VMC, ACOS/R, to the IACUC c/o the RCO, to the IACUC Chair, or to the IO. Mechanisms for reporting concerns are posted in the animal facilities with instructions on reporting animal welfare concerns and who to contact.

This reporting-feedback mechanism of observations regarding the practices of animal care and use within these laboratories, contributes an important oversight, and assists in the continuous development of the animal program.

Such reports, suggestions, complaints, or questions are made with complete protection of the reporting individual from any discrimination or reprisal and can be made anonymously.

The IACUC deliberates regarding the reported alleged deficiency at its next regularly scheduled monthly meeting, or the IACUC Chair can call an emergency meeting to discuss the issue in advance of a regular meeting if deemed necessary. The IACUC Chair can choose to invite involved personnel to the meeting to whom questions can be directed. The IACUC reports the findings of its deliberations in writing to the PI (for corrective action) and the Institutional Official.

When a significant non-compliance is identified or an approved protocol suspended, the appropriate federal agencies are notified by the IO (IACUC notifies ACOS/R, IO, R&DC, ORO, CVMO, USDA, OLAW, and AAALAC within 5 business days).

4. **Disaster Planning and Emergency Preparedness** [*Guide* p. 35]
Briefly describe the plan for responding to a disaster potentially impacting the animal care and use program:
- Identify those institutional components and personnel which would participate in the response.
- Briefly describe provisions for addressing animal needs and minimizing impact to animal welfare.

Note: A copy of disaster plan(s) impacting the animal care and use program must be available for review by the site visitors.

The individual with overall responsibility is the IO or designee (e.g., ACOS/R, VMC, and Managing Director of VMU). In the event of an emergency involving an animal housing area, the Managing Director of VMU and VMC must be contacted. For an emergency involving a hazardous material (biological, chemical, physical, radiological), the applicable safety officer (BSO, Radiation Safety Officer, IH) is contacted.

Provisions for addressing animal needs to minimize the impact to animal welfare include:
- Performing animal health checks as soon as possible after an emergency.
- Replacing any compromised feed. Standard diets may need to be replaced with alternative diets if required. A two-week supply of standard diets is maintained in each facility.
- If there is an interruption to the water supply, water can be obtained from another facility or from a commercial source. Water provided will be potable and, ideally, delivered in the same form (e.g., RO) as normal.
- Routine sanitation will resume as soon as possible assuming equipment is functional. If equipment is not functional, alternate method(s) are available (e.g., hand washing, use equipment in other facilities). In addition, less critical activities (e.g., mopping floors) may be deferred.
- In the event there is a loss of power, lighting, temperature control, and/or HVAC or there is environmental contamination (e.g., smoke, chemicals), each facility is equipped with methods to control minor variations (e.g., portable cooling units, fans, increasing the exhaust). However, in cases of serious damage to environmental systems, animals could relocate to alternate facilities as determined

by the ACOS/R, VMC or Managing Director of VMU.

II. Animal Environment, Housing and Management

Note: Complete each section including, where applicable, procedures performed in farm settings, field studies, aquatic environments, etc.

A. Animal Environment

Note: Facility-specific details regarding mechanical system construction and operation is requested in Section IV.B.5. and **Appendix 11**; current (measured ***within the last 12 months***), detailed (by room) performance data must also be provided as indicated in **Appendix 11.**

1. Temperature and Humidity [*Guide*, pp. 43-45]

a. Describe the methods and frequencies of assessing, monitoring, and documenting that animal room or housing area temperature and humidity is appropriate for each species.
Note: If preferred, this information may be provided in a Table or additional Appendix.

The animal care staff takes morning temperature and humidity readings daily recording the high, low and current readings for the room over the past 24 hours in individual animal rooms including weekends and holidays. This is documented on the animal room log sheets that are maintained in each room. The thermostats are also monitored continuously (24 hours/day) by both a Johnson Controls system that relays to engineering service and the Edstrom Watchdog system that relays to the Managing Director's cell phone. When outside of a pre-assigned range, the Managing Director and the boiler plant supervisor are notified of the problem. The Managing Director then contacts the boiler plant supervisor to verify the problem and an appropriate plan developed and acted upon.

b. List, by species, set-points and daily fluctuations considered acceptable for animal holding room temperature and relative humidity.
Note: If preferred, this information may be provided in a Table or additional Appendix. [*Guide*, pp. 44 and 139-140]

All animal room temperatures are maintained at temperatures recommended in the *Guide* appropriate for each species. Animal r(b)(6) and (b)(run off of a separate air handler from the rest of the facility and uses 100% outside air for its supply. The rest of the facility including animal (b)(6) are supplied off of a different air handler which also supplies the rest of (b)(6) This air handler is also supplied with 100% outside air. All room temperatures can be adjusted by the main controls maintained by engineering service.

Mouse and rat room set points are currently:

For the Johnson Controls/Aircuity system (Does not monitor RH):

(b)(6)	Temperature Set Point (°F)	Low Alarm (°F)	High Alarm (°F)
	70.8 ± 0.5	65	75
	71 ± 0.5	65	76
	70 ± 0.5	65	75
	70.6 ± 0.5	65	76
	71 ± 0.5	65	76
	70 ± 0.5	65	76
	70 ± 0.5	60	76
	70 ± 1.0	60	76
	68 ± 2.0	65	75

For the Watchdog Environmental Monitoring System – Alarm Set points

	Temp Low/Low critical	Temp High/High critical	Humidity L/H
All Holding rooms	64/62	81/83	30/70

c. Temperature set-points in animal housing rooms and/or environmental conditions are often outside of the species-specific thermoneutral zone. Describe the process for enabling behavioral thermoregulation (e.g., nesting material, shelter, etc.) or other means used to ensure that animals can control their thermoregulatory environment. Include a description of IACUC/OB approved exceptions, if applicable. [*Guide*, p. 43]

Set points for temperature are within the recommended ranges set forth in the *Guide* for all species.

If for some reason the room temperatures fall outside of the thermoneutral zone due to a power outage or other extenuating factor, engineering service can provide mobile air conditioners or heaters to help return rooms to proper range until the problem is resolved.

We have no current requests or approvals for having any rooms intentionally kept out of range.

We have an ongoing documented issue with keeping the humidity within the recommended ranges year-round. This is an HVAC issue that we have been working on with engineering service. Since we have not successfully resolved the issue, we continually monitor the health of the animals and watch for issues caused by either high (in the summer months) or low (in the winter months) humidity. So far, VMU staff has not observed animal health issues associated with increased or decreased humidity levels at the room level.

2. Ventilation and Air Quality [*Guide*, pp. 45-47]

a. Describe the methods and frequencies of assessing, monitoring, and documenting the animal room ventilation rates and pressure gradients (with respect to adjacent areas).
Note: If preferred, this information may be provided in a Table or additional Appendix.

Engineering service inspects the animal room ventilation annually as well as hires a contractor to conduct our air balancing report. More frequent QC and preventative maintenance is performed on the air ducts, and air handling system. The entire animal facility uses only 100% fresh HEPA filtered air. The acceptable general standard for secondary enclosures is a minimum of 10-15 fresh-air changes per hour.

Since our last site visit, we have a new air quality monitoring system put in place. The Aircuity System is an integrated sensing and control solutions that monitors and improves indoor environmental quality in lab spaces. The Aircuity Platform uses unique and proprietary technologies to provide remote sampling connected to a centralized sensing architecture which continuously measures multiple indoor air parameters. In (b)(6) the Aircuity system samples for TVOCs, particulate, and CO2. In (b)(6), it monitors the same parameters as in (b)(6) plus humidity. If these monitored items exceed prescribed limits, the Aircuity system sends a command to the Building Automation System to increase airflow rates into the room. The centralized sensors cycle through all rooms connected to the sensor suite in less than 15 minutes. Airflow rates in rooms along with temperature are trended in the Building Automation System every 15 minutes.

In (b)(6), differential pressure between a room and the corridor is measured by a dp sensor that controls an exhaust damper to maintain a constant pressure difference. The pressure reading for a room is trended every 15 minutes.

In (b)(6), differential pressure between a room and the corridor is maintained by an air valves in the supply and exhaust maintaining a set differential in supply air and exhaust air. A pressure sensor records the pressure differential every 15 minutes.

Corrective action is taken as quickly as possible for any abnormalities.

b. Describe ventilation aspects of any special primary enclosures using forced ventilation.

A majority of mouse colonies are housed on ventilated racks with an automatic watering system. The racks receive approximately 35 air changes per hour via a HEPA filtered air supply unit.

c. If any supply air used in a room or primary enclosure is recycled, describe the percent and source of the air and how gaseous and particulate contaminants are removed.

All of our rooms are supplied with 100% fresh air

3. Life Support Systems for Aquatic Species [*Guide*, pp. 84-87]

a. Provide a general description of institutional requirements for enclosures using water as the primary environmental medium for a species (e.g., aquatics).

Not Applicable

b. Provide a general description of overall system(s) design, housing densities, and water treatment, maintenance, and quality assurance that are used to ensure species appropriateness.
Note: Facility-specific tank design and parameter monitoring frequencies should be summarized in **Appendix 12** (Aquatic Systems Summary).

Not Applicable

4. Noise and Vibration [*Guide*, pp. 49-50]
Describe facility design features and other methods used to control, reduce, or prevent excessive noise and vibration in the animal facility.

(b)(6) have drywall ceilings in all rodent housing rooms. Some areas hallways have drop ceilings, which helps absorb sound. In an effort to reduce animal noise. All rodent room doors are kept closed as much as possible (not to be propped open for extended periods of time) so noise from the machines and carts in the halls do not disturb animals. Fire alarms are set below rodent hearing frequency.

With our new building under construction, we have been paying close attention to abnormal behavior due to possible noise or vibration irritation to the animals. So far there have been no noticeable adverse events.

B. Animal Housing (all terrestrial, flighted, and aquatic species)

1. Primary Enclosures

Note: A description of primary enclosures used (e.g., cages (conventional, individually-ventilated cage systems (IVCS), etc.), pens, stalls, pastures, aviaries, tanks) should be included in **Appendix 13**.

a. Describe considerations, performance criteria and guiding documents (e.g. *Guide*, *Ag Guide*, ETS 123 and/or other applicable standards) used by the IACUC/OB to verify adequacy of space provided for all research animals, including traditional laboratory animal species, agricultural animals, aquatic species, and wildlife when reviewing biomedical, field and agricultural research studies.

All space requirements are determined based on the recommendations in the *Guide* to determine adequacy of space for each species. We currently use both conventional and IVC cages for rodents. Primary enclosures which provide the limits of an animal's immediate environment must:

a. Allow for the normal physiologic and behavioral needs of the animals, including urination and defecation, maintenance of body temperature, normal movement and postural adjustments, and, where indicated, reproduction.
b. Allow nonspecific social interaction and development of hierarchies within or between enclosures.
c. Make it possible for the animals to remain clean and dry (as consistent with the requirements of the species).
d. Allow adequate ventilation.
e. Allow animals access to food and water and permit easy filling, refilling, changing, servicing, and cleaning of food and water utensils.
f. Provide a secure environment that does not allow escape of or accidental entrapment of animals or their appendages between opposing surfaces or by structural openings.
g. Are free of sharp edges or projections that could cause injury to the animals.
h. Allow observation of the animals with minimal disturbance of them.

b. Describe space exceptions to the guiding documents (*Guide*, *Ag Guide*, ETS 123, and/or applicable standards), indicating the references, considerations and performance criteria used (e.g., by the IACUC/OB) to verify adequacy of space provided for all animal species covered by the program. [*Guide*, pp. 55-63]

We currently have one protocol which contains approved exceptions/departures to the *Guide*'s space recommendations. These exceptions have been specifically reviewed and approved by the IACUC based on the scientific justification or animal welfare consideration. They include:

(b)(6)

Transgenic mouse model of breast cancer that develops mammary tumors upon the expression of mouse mammary tumor virus (MMTV). MMTV constructs are more active with elevated pregnancy hormones (Estrogen and Progesterone). Therefore, in order to initiate mammary tumor formation in a timely manner, mice must be continuously mated to shorten tumor latency and increases tumor incidence. There was a 24hr grace period to remove born pups from those harem cages that may have been overlooked.

2. Environmental Enrichment, Social, and Behavioral Management [*Guide*, pp. 52-55; 63-65: *Ag Guide*, Chapter 4]

a. Environmental Enrichment

i. Describe the structural elements of the environment of primary enclosures that may enhance the well-being of animals housed (e.g., resting boards, privacy areas, shelves/perches, swings, hammocks).

The structural environment, when indicated, will include equipment that increases opportunities for the expression of species-typical postures and activities to enhance the animals' well-being.

Depending on the animal species and use, the structural environment may consist of components of the primary enclosure, e.g. resting boards, shelves or perches.

Environmental enrichment is species specific and we make every effort to provide adequate enrichment opportunities for our animals.
(See SOP on Environmental Enrichment for Laboratory Animals VMU 010), available on site.

ii. Describe nonstructural provisions to encourage animals to exhibit species typical activity patterns (e.g., exercise, gnawing, access to pens, opportunity for exploration, control over environment, foraging, denning, burrowing, nesting materials, toys/manipulanda, browsing, grazing, rooting, climbing).

Equipment for environmental enrichment or objects for manipulation by the animals is provided unless scientific justification to withhold enrichment has been reviewed and approved by the IACUC.
Mice: Nestlets, nylabones, crinkle paper, disposable huts, polycarbonate/PVC huts, paper tubes
Rats: Nylabones, paper towel, paper tubes, plastic rodent tubes, crinkle paper
Hamster: Nestlets, nylabones, crinkle paper, disposable huts, polycarbonate/PVC huts

b. Social Environment [*Guide*, p. 64]

i. Describe institutional expectations or strategies for social housing of animals.

The social environment usually involves physical contact and communication among members of the same species (conspecifics), although it can include noncontact communication among individuals through visual, auditory, and olfactory signals.

Social animals are housed in physical contact with conspecifics. However, experimental, health, and behavioral reasons might preclude this kind of housing.

ii. Describe exceptions to these expectations (e.g., veterinary care, social incompatibility) and other typical justification approved by the IACUC/OB for housing animals individually.

The use of solitary housing of social animals must be scientifically or medically justified. When they must be housed alone, like in the case of males due to fighting or having been separated from a female, other forms of enrichment are provided to compensate for the absence of other animals, such as safe and positive interaction with the care staff and enrichment of the structural environment. Justification for single housing of social species may include:
(1) Scientific requirement – Animals may need to be housed in specialized cages (e.g., metabolic cages) to obtain data. Exteriorized implants (e.g., brain or venous cannulas) or surgical incisions may be damaged by cage mates. Animals on regulated food or fluid intake studies may require single housing.
(2) Veterinary health/animal welfare – Animals may be single housed due to veterinary health or animal welfare concerns. Animals with unknown health status may be single housed to minimize/prevent potential for cross-contamination of conspecifics. Injured, sick or, post-surgical animals often require single housing to aid in recovery. Animals known to have an aggressive phenotype require single housing to prevent injury to cage mates. Pregnant females are often separated to prevent overcrowding based on cage space requirements.
(3) Other – Death or termination for experimental reasons of a cage mate may result in a single housed animal. When rodent pups are weaned, the number of pups may not allow for all animals in a litter to be placed with a compatible cage mate (e.g., single male pup in a litter).

iii. Describe steps taken with isolated or individually housed animals to compensate for the absence of other animals (interaction with humans, environmental enrichment, etc.).

Rodents housed individually are provided with additional enrichment items, unless a request to withhold enrichment for scientific reasons was reviewed and approved by the IACUC. The IACUC has approved a policy for environmental enrichment of rodents.

c. Enrichment, Social and Behavioral Management Program Review [*Guide*, pp. 58, 69]

Describe how enrichment programs and exceptions to social housing of social species are regularly reviewed to ensure that they are beneficial to animal well-being and consistent with the goals of animal use.

According to our "CVAMC Animal Care and Use Program Policy, Guidelines and

Procedures," all SOP's are reviewed by the IACUC on an annual basis. This would include the Enrichment SOP. If animal care staff finds new enrichment devices or products, they are discussed with the veterinarian and Managing Director and added to the SOP for approval by the IACUC. Any exceptions or deviations from the *Guide*'s recommendations on social housing and enrichment must be approved by the IACUC in an ACORP for any PI to use the requested methods or enrichment.

d. Procedural Habituation and Training of Animals [*Guide*, pp. 64-65]
Describe how animals are habituated to routine husbandry or experimental procedures, when possible, to assist animals to better cope with their environment by reducing stress associated with novel procedures or people.

In one approved rat study, the rats have their mouth routinely swabbed. To make this procedure less stressful, the technicians condition them by offering a treat after the swab to "reward" the good behavior. The animals become very calm and relaxed with this conditioning, making for a less stressful experience.

Another study where rats have cannula implants, the lab techs handle the rats daily to clean the cannula and condition them to being comfortable with the cannula being touched prior to the actual treatment studies taking place.

e. Sheltered or Outdoor Housing [*Guide*, pp. 54-55]

i. Describe the environment (e.g., barn, corral, pasture, field enclosure, flight cage, pond, or island).

Not Applicable

ii. Describe methods used to protect animals from weather extremes, predators, and escape (windbreaks, shelters, shaded areas, areas with forced ventilation, heat radiating structures, access to conditioned spaces, etc.).

Not Applicable

iii. Describe protective or escape mechanisms for submissive animals, how access to food and water is assured, provisions for enrichment, and efforts to group compatible animals.

Not Applicable

f. Naturalistic Environments [*Guide*, p. 55]

i. Describe types of naturalistic environments (forests, islands) and how animals are monitored for animal well-being (e.g., overall health, protection from predation).

Not Applicable

ii. Describe how food, water, and shelter are provided.

Not Applicable

iii. Describe how animals are captured.

Not Applicable

C. Animal Facility Management

1. Husbandry

a. Food [*Guide*, pp. 65-67]

i. List type and source of food stuffs.

Purina Lab Diet chows are used for the various animal species except when special, research formulated, diets prepared by technicians of individual investigators or commercially prepared diets as required by the needs of the individual studies.

General Maintenance Diets:
Rodents Purina, Autoclavable Rodent diet #5010
Rodents Purina, Autoclavable Mouse Breeder Diet #5021
Rodents Purina Irradiated Rodent #5053

ii. Describe feed storage facilities, noting temperature, relative humidity, and vermin control measures, and container (e.g., bag) handling practices, for each of the following:

- vendors (if more than one source, describe each)
- centralized or bulk food storage facilities if applicable
- animal facility or vivarium feed storage rooms
- storage containers within animal holding rooms

Vendors: Cincinnati Lab Supply Internal Sanitation and Quality Control Program: In addition to the Terminix Pest Control program, Cincinnati Lab Supply internal sanitation and quality control includes:

- All outside and inside devices are checked and logged weekly. Any activity is noted to pinpoint problem areas.
- All incoming products are visually inspected for damage or infestation.
- All certified lab chows are logged by manufacturer date codes, customer's name, purchase date, and quantity purchased-this enables the tracking of a

particular product if necessary.

- All products are rotated by date to ensure freshness.
- All products are stored on pallets and pallet racking off the floor and 18" inches from the walls.
- An 18" space painted white on the floor along the perimeter of the walls for easy inspection of any insect or rodent activity.
- All doors and windows are kept shut and are adequately sealed to prevent potential pest entry.
- The warehouse building is a modern facility constructed of concrete block and steel. The floors are smooth concrete and all joints are caulked and sealed. The outside is surrounded by blacktop.
- The entire warehouse is heated and a section of the warehouse is air conditioned for feed storage to control the heat and humidity in the summer months. The temperature is set at 68°F.
- The floors and delivery equipment are swept daily to avoid infestation from spillage.
- Outside surroundings are kept free of weeds and debris.

Animal Facility Storage: Two rooms in (b)(6) and one room in (b)(6) are dedicated to feed storage within our animal care facilities. All animal food is stored on racks or pallets, away from walls to facilitate cleaning and sanitation. The floor is swept and mopped at least 2-3 times per week. The room is periodically emptied and thoroughly cleaned and sanitized quarterly. Storage room average temperature is 65-72°F throughout the year.

Storage containers within animal rooms: Bags of feed are stored in plastic barrels or feed bins in individual animal rooms, along with small quantities of food stored in containers in the changing hood for easy access. The food storage barrels are lined with a can liner, the manufacturer bag is within the liner so the milling information is available. All of the barrels or bins possess tightly fitting lids, secured so as to protect the food from moisture, vermin and other potential contamination. Feed bins are sanitized monthly.

iii. Describe special food preparation areas, such as feedmills and locations where special diets are formulated, if applicable. Include in the description sanitation and personnel safety practices (noting that respiratory protection is described in Section 2.I.A.2.b. ii. Standard Working Conditions and Baseline Precautions above).

No food preparation areas are used.

iv. Describe how food is provided to various species (*ad libitum*, limited amounts, types of feeders).

Food is provided ad-libitum in either a wire bar cage top or a hanging feeder within the cage.

v. Describe special food quality control procedures including procedures for rotating stock, monitoring milling dates, nutritional quality, bio load, chemical contaminants, etc.

Each food bag is inspected for damage and dated on arrival at the CVAMC animal facilities. Damaged bags are returned to the vendor or discarded. Nutritional quality is provided by the manufacturer. All feed is used or discarded within the time period after milling specified by the manufactures, typically within 9 months post milling. Biological and chemical analysis is not being performed on food products at this time due to the nature of our research. Each feed barrel is labeled with type of feed, mill date, 9-month expiration date, order # and the date the barrel was sanitized. As feed comes in, stock is rotated so it is used first in, first out.

b. Drinking Water [*Guide*, pp. 67-68]

i. Describe the water source, treatment or purification process, and how it is provided to the animals (e.g., bowls, bottles with sipper tubes, automatic watering, troughs, ponds, streams).

The VMU uses water from the municipal water supply as purified for human consumption. In (b)(6) all rodents are supplied water either by bottles with sipper tubes or by an automatic watering system. Some mouse bottles are autoclaved prior to use. The automatic watering system provides purified water to all automatic watering racks which house mice in four rooms. The water goes through 5μ, 1μ and 0.2μ filters prior to consumption. Some animals, by request of the PI, receive autoclaved bottles and water.

In (b)(6) the animal watering system is fed via a reverse osmosis system (Edstrom). If for some reason that system is down, the automatic watering can be switched over to a filtering system like the one described for (b)(6) Some animals may be on water bottles as well by request.

Two PIs utilized acidified water either for immunosuppressed or immunocompromised mice

ii. Describe methods of quality control, including monitoring for contaminants.

Water is monitored for contamination by visual inspection and by means of the Ruhof Aquaswab ATP luminometer test to detect residual ATP as an indicator of potential bacterial growth. The automatic watering system is flushed with high pressure water 4 times daily to prevent stagnant water. Every three-six months the system is sanitized and filters are checked and/or changed approximately every 6 months (as needed by Edstrom technicians). The watering system has preventative maintenance every 6 months. Water bottles are sanitized in the cage washing machine at a guarantee temperature of 182°F. The sippers are soaked in bleach water prior to going through the washer. For certain studies, filled water bottles with sipper tubes are autoclaved.

iii. If automatic water delivery systems are used, describe how they are maintained and sanitized.

The automatic watering system is flushed with high pressure water four times daily to prevent stagnant water. Approximately every three months the system is sanitized with a mild bleach solution and filters are checked and/or changed on a monthly, quarterly or as needed basis, all according to the manufacturer's guidelines. We also have preventative maintenance service done semi-annually.

c. Bedding and Nesting Materials [*Guide*, pp. 68-69]

i. Describe type(s) and how used for various species.

Depending on the cage type and/or needs of the experiment direct or indirect bedding is used as follows:

Species	Methods	Types	Storage
Rodents	Direct	Autoclaved Bed-O-Cobs Autoclaved Sani-Chip	Unopened bags on pallets/transport cart in feed/bedding room
Rodents	Indirect	Cage boards, metabolic cages	
Rodents	Nesting materials	Nestlets, Crinkle Paper, Paper	Boxes on shelving units/carts in feed/bedding room; autoclaved in covered cage in housing room

ii. Describe bulk bedding storage facilities, if applicable, including vermin control measures.

Bedding is stored off the floor on carts or racks in two locations in (b)(6) (b)(6) has a Feed and Bedding storage room just inside the loading dock. Feed is stored off the floor on dunnage racks. Temperature and humidity parameters are monitored daily in all feed/bedding storage locations by the hygrometers. Bedding/feed room doors are equipped with door sweeps to prevent vermin. Insect traps are utilized if a problem is suspected. Open bags of bedding are not stored in bedding/feed rooms.

iii. Describe quality control procedures, including monitoring for contaminants.

Bedding is monitored for contamination by visual inspection. Quality control data is available from the supplier. Bedding is rotated in a first in - first out method as for food and is autoclaved prior to use either in the bag or in cages. Bedding is stored on transport carts or dunnage racks, off the floor, away from the walls in combined feed/bedding rooms at temperatures <70°F as recommended by the *Guide* (for feed storage). Temperature and humidity parameters are monitored daily in all feed/bedding dedicated storage locations by the building automated system and/or a hygrometer. Feed/bedding storage areas/rooms are swept and mopped at least weekly and sanitized at least every six months. Insect traps are available if a problem is suspected.

d. Miscellaneous Animal Care and Use Equipment

i. Describe motorized vehicles and other equipment (e.g., trailers) used for transporting animals, noting the type and how the cargo compartment is environmentally controlled, if applicable.

Animals transported between UC and VA facilities are done so in a designated UC facility box truck or cargo van that is climate controlled for this purpose.

2005 Dodge Mini-Caravan Cargo Van: (b)(6) is equipped with bulk head, heat, air conditioning, and tinted windows to protect the animal and/or cage from direct sunlight.

2010 Mitsubishi Fuso Box Truck: (b)(6) is equipped with a hydraulic lift gate and climate controlled custom designed box for secure transport of animals and equipment.

Animals going between VA and CCHMC can be transported in a personal vehicle as long as the vehicle is climate controlled. All drivers are protected by the filtered shipping containers that are used so allergens and/or hazards are contained.

ii. Describe other animal care related equipment used in the animal care program (specialized equipment for exercise or enrichment, high pressure sprayers, vacuum cleaners, tractors, trailers, spreaders, etc.).

When animal rooms are empty or between study groups, a hydro-foamer is used to completely and thoroughly sanitize the walls and floors. We have both a portable foamer and a hose sprayer foamer that hooks directly to a wall faucet.

e. Sanitation [*Guide*, pp. 69-73]

i. Bedding/Substrate Change

1) Describe frequency of contact and non-contact bedding change for each species and enclosure type (solid-bottom or suspended) or pen.

Rats, mice and hamsters are housed in polycarbonate cages. Cages of animals housed in PIV racks are cleaned and sanitized weekly or every other week, depending on the number of animals in the cage. Animals in conventional cages are cleaned and sanitized 1-3 times per week, depending on the number of animals in the cage. Mice in metabolism cages are housed in them less than seven days. Cages are sanitized between study groups.

2) Describe any IACUC/OB approved exceptions to frequencies recommended in the *Guide* or applicable regulations and the criteria used to justify those exceptions.

There are no IACUC approved exceptions to the cage changing frequency recommended by the Guide.

3) Note the location where soiled bedding is removed from the cages/enclosures and where clean bedding is placed into the cages/enclosures.

For mouse cages, bedding is placed in clean cages outside of the cage wash area for autoclaving. Rat cages are unloaded on the clean side of the cage wash and bedded with autoclaved bedding and placed into storage. Hamster cages are handled following ABSL-2 handling procedures.

Transfer of animals into clean cages is performed in the animal room either in a BSC or on a cart depending on the species and study.

The dirty cages and soiled bedding is removed from the room and the bedding bagged in (b)(6) in a cage dump station or (b)(6) in (b)(6) in a downdraft dumping station. Special procedure outlined previously is used for the ABSL-2 cages and bedding.

ii. Cleaning and Disinfection of the Micro- and Macro-Environments

Note: A description of the washing/sanitizing frequency, methods, and equipment used should be included in **Appendix 14** (Cleaning and Disinfection of the Micro- and Macro-Environment) and **Appendix 15** (Facilities and Equipment for Sanitizing Materials).

1) Describe any IACUC/OB approved exceptions to the *Guide* (or applicable regulations) recommended sanitation intervals.

There are no IACUC approved exceptions to the *Guide* recommendations for sanitization intervals.

2) Assessing the Effectiveness of Sanitation and Mechanical Washer Function

a) Describe how the effectiveness of sanitation procedures is monitored (e.g., water temperature monitoring, microbiological monitoring, visual inspections).

The temperature of the mechanical washer is logged weekly by temperature tape operation to ensure that the appropriate temperature (180°F) is maintained to sanitize equipment. We also use a Ruhof ATP tester to swab cages and other surfaces to ensure sanitation was achieved. Autoclave integrator strips, OK test strips and 3M biological indicators (#1292) are also used in the sterilizer to ensure proper temperature is reached and there is no biological contaminants are present.

b) Describe preventive maintenance programs for mechanical washers.

We have preventative maintenance service performed by a contracted service vendor on our washers and autoclaves quarterly or as needed.

f. Conventional Waste Disposal [*Guide*, pp. 73-74]
Describe the handling, storage, method and frequency of disposal, and final disposal location for each of the following:

i. Soiled bedding and refuse.

Soiled bedding is separated into 2 classes: that from biohazardous rooms and that from nonhazardous rooms. The bedding from nonhazardous rooms remains in the cages until they are moved to the cage dump area in (b)(6) or (b)(6) There the bedding is emptied into plastic bags in a HEPA-filtered cage dump station. When the trash cart is full or at the end of the day, the contents are transferred to the dumpster adjacent to (b)(6) The dumpster is exchanged 2 times per week and transported to a privately-owned landfill. The biohazardous bedding waste is autoclaved prior to disposal.

Soiled bedding from biohazardous rooms is changed in the room within a Class II-A2 BSC, marked as biohazardous waste, and autoclaved prior to disposal. Sharps containers are collected when full. All biohazardous material is placed in a room labeled "Bio-Hazard Material", located by the dumpster until incinerated by a private contractor. Glass is collected in puncture proof boxes, sealed up and discarded in the dumpster.

ii. Animal carcasses.

Animal carcasses are placed in plastic bags and stored in a freezer. Carcasses are then transferred to the hospital biohazard room. Daily, a private contractor whose incinerator has met all State of Ohio Environmental Protection Agency guidelines for burning for pathologic waste picks up our animal carcasses along with the hospital waste for incineration.

g. Pest Control [*Guide*, p. 74]

i. Describe the program for monitoring and controlling pests (insects, rodents, predators, etc.). Include a description of:

- monitoring devices and the frequency with which devices are checked
- control agent(s) used and where applied, and
- who oversees the program, monitors devices, and/or applies the agent(s).

The primary method to control insects and rodents is through good sanitation practices. However, on visual detection of roaches or other pests, a licensed pest contractor is called to apply gel bait, bait stations and or sticky traps.

ii. Describe the use of natural predators (e.g., barn cats) or guard animals (e.g., dogs, donkeys) used for pest and predator control, if applicable.

Not Applicable

iii. Note how animal users are informed of pesticide use and how animal users may opt out of such use in specific areas.

The Managing Director of the VMU will notify an investigator of a pest problem within his/her animal room and recommend that the room be treated with a pesticide. There are no anticipated complications of baiting within the animal rooms.

h. Weekend and Holiday Animal Care [*Guide*, pp. 74-75]

i. Describe procedures for providing weekend and holiday care. Indicate who (regular animal care staff, students, part-time staff, etc.) provides and oversees care and what procedures are performed.

The responsibility for weekend and holiday coverage is to provide care for animals, rests with one animal care staff member each weekend. Their duty includes a visual check of all animals, necessary watering, feeding, changing any cages that appear wet, dirty, etc. A list of responsible individuals and their telephone numbers is posted in each animal care area so that, should problems arise regarding animal care or animal health, they can be addressed immediately. AV/VMC is available for all emergency care on weekends, holidays and after hours via cell phone. When AV/VMC is not available, he communicates to the other veterinarian from UC for coverage in his absence.

ii. Indicate qualifications of weekend/holiday staff if not regular staff.

Our regular staff covers all weekends and holidays

iii. Describe procedures for contacting responsible animal care and/or veterinary personnel in case of an emergency.

A list of responsible individuals (researchers) and their telephone numbers is posted in each animal care area so that, should problems arise regarding animal care or animal health, they can be addressed immediately. AV/VMC is available for all emergency care on weekends via cell phone. When AV/VMC is not available, he communicates to other veterinarian in the department for coverage in his absence

2. Population Management [*Guide*, pp. 75-77]

a. Identification

Describe animal identification methods for each species (e.g., microchips, cage/tank cards, collars, leg bands, tattoo, ear tags, brands).

For rats, mice and hamsters, cage cards are maintained on each cage containing the following information: date of arrival or date of weaning; birth date; investigators name; protocol number; source; strain; identification number if applicable; sex and age. Animals can be further identified by ear tag, ear punch or tattoo.

b. Breeding, Genetics, and Nomenclature

i. Describe the program for advising investigators on the selection of animals based on genetic characteristics.

The VMC is available to all researchers for consultation as needed. The choice of animal strain is then monitored and/or changes recommended by the IACUC at the time of protocol preliminary review process. Investigators also consult the current literature and their expertise in selecting animal models based on genetic characteristics.

ii. Describe the program for advising investigators on using standardized nomenclature to ensure proper reporting of the identification of the research animals with regard to both the strain and substrain or the genetic background of all animals used in a study.

It is requested that cage cards are filled out thoroughly and accurately with the correct nomenclature, especially where there are many genetic crosses being used in one colony. If many strains are used by one PI, we ask that they label them with color coded dots so we can easily identify the strains.
Books and reference materials (e.g., The Jackson Laboratories Mouse Genome Informatics database) defining standard genetic nomenclature are available either through the animal vendors or the Managing Director has some strain listings by vendor.

iii. Describe genetic management techniques used to assess and maintain genetic variability and authenticity of breeding colonies, including recordkeeping practices (*Guide*, pp. 75-76).

Researchers are encouraged to keep detailed breeding information in a manner as to make tracking offspring simple (e.g., sire/dam number, date and number born, date and number weaned, how offspring are used [e.g., replacement breeders, experimental subjects], euthanasia/deaths [date and reason]). The VMC provides information to researchers on how to manage breeding colonies and tips/strategies to minimize chances of strain contamination (e.g., keeping adjacent cages/strains as phenotypically and genotypically distinct as possible, using different color coded dots on cage cards to make each colony visually distinguishable. The VMC and/or Managing Director of VMU also invites experts from the commercial vendors to seminar series to present on breeding colony management strategies. To avoid substrain divergence in transgenic colonies, it is recommended to backcross to the parental strain every 10 generations.

iv. For newly generated genotypes, describe how animals are monitored to detect phenotypes that may negatively impact health and well-being. Note that the methods used to report unexpected phenotypes to the IACUC/OB should be described in section 2.1.B.1.c.ii, "Unexpected Outcomes that Affect Animal Well-Being."

Management of the condition will depend on the type of illness present but will be conducted in conjunction between the PI and veterinarian with approval of the IACUC to ensure the animal health and well-being. If this should arise, a notice will be posted in the room for what to look for in the colony and what care is needed. The Managing Director will notify the VMC and the VMC will decide how to proceed to ensure the animal's well-being.

III. Veterinary Care [*Guide*, pp. 105-132]

Note: Complete each section, including, where applicable, procedures performed in farm settings, field studies, aquatic environments, etc.

A. Animal Procurement and Transportation [*Guide*, pp. 106-109; *Ag Guide*, pp. 8; 45; 50-57]

1. Animal Procurement

Describe the method for evaluating the quality of animals supplied to the institution (from commercial vendors, other institutions, etc.).

The investigators define the strain and stock of rodent species required for their studies. Potential sources of animal purchase are then evaluated usually based on past performance and firm reputation. Vendors carry out serologic, parasitological and microbiologic monitoring for the important diseases of that species and we carry out similar testing on sentinel animals quarterly in our facility. For the most part, rodent suppliers are approved vendors who reliably provide healthy, virus antibody-free animals. All vendors are licensed. Animals from approved vendors are evaluated upon receipt by VMU animal care staff and directly admitted into the main population. If a health problem originates at the vendor or develops during transportation, Managing Director and/or VMC works with the vendor to resolve the problem. When receiving animals from other institutions, the past year of Serology, endo and ecto parasite results are requested and reviewed by the VMC. Once the VMC deems them "clean", arrangements can be made to have them transferred to the VMU quarantine room.

2. Transportation of Animals

Describe how animals are transported between outside sources and the institution and within the institution, including loading, unloading, level of biosecurity, immune status and specific pathogen status (consider all species, including aquatic and semi-aquatic species).

Animals are transported to the VMU either via the supplier's commercial vehicle or delivered via overnight air carrier. Animals arriving from vendors are shipped in sterile microisolator shipping crates. Upon arrival, receiving personnel check the condition of the shipping containers and verify the purchase requisitions prior to acceptance. The outside surfaces of the box is sprayed or wiped down with Clidox prior to opening. Animals are unpacked in the BSC and placed in cages. Rodent shipments from non-approved vendors are handled the same as for approved vendor sources with the exception of placing in a quarantine room.

Transportation to or from UC is in UC's climate controlled box truck or cargo van. Transport of rodents in personal vehicles is allowed upon approval from the Managing Director and/or VMC. The transport of animals in these vehicles is "one way" as rodents are not allowed back into the facility. Drivers are re-informed of the potential allergen exposure in such situations and requirement for temperature control in the transport vehicle.

When transferring animals between VA and UC or CCHMC, the same individual may not pack and unpack the animals.

B. Preventive Medicine

1. Animal Biosecurity [*Guide*, pp. 109-110]

a. Describe methods used to monitor for known or unknown infectious agents. Note that if sentinel animals are used, specific information regarding that program is to be provided below.

Sentinel animals are used for quarterly monitoring for the presence of known infectious agents of rodents housed in all rodent rooms. To monitor for unknown infectious agents, necropsy examinations are performed when animals die unexpectedly or exhibit unusual symptoms. If necessary, cultures can be taken and sent out for evaluation. The ectoparasites and endoparasites will be checked quarterly on all sentinel animals used for serologic monitoring. Fecal flotation, microscopic examination of cecum/colon contents, pelt examinations, fur pluck and perianal tape tests are examined in-house at postmortem. Fecal flotation and perianal tape testing is used for detection/monitoring of pinworms. Serology and/or PCR is performed by an outside laboratory (e.g., IDEXX RADIL). Fur pluck and fur swab PCR testing is utilized for detection/monitoring of fur mites. Serology is performed for detection/monitoring of bacterial or viral agents.
All mouse colonies are tested at least quarterly for Mouse Basic Panel and annually for Mouse Comprehensive Panel:

Mouse Panel Tests	Mouse Basic	Mouse Comprehensive
Mouse Hepatitis Virus (MHV)	X	X
Minute Virus of Mice (MVM)	X	X
NS1 (generic Parvovirus)	X	X
Mouse Parvovirus panel 1-5 (MPV)	X	X
Mouse Norovirus (MNV)	X	X
Theiler's virus (TMEV)	X	X
Mouse Rotavirus (Epizootic Diarrhea of Infant Mice, EDIM)	X	X
Sendai virus (SV)	X	X
Mycoplasma pulmonis (MPUL)	X	X
Pneumonia Virus of Mice (PVM)	X	X
Reovirus 3 (REO3)	X	X
Lymphocytic Choriomeningitis Virus (LCMV)	X	X
Ectromelia Virus	X	X
Mouse Adenovirus 1 (MAV1)		X
Mouse Adenovirus 2 (MAV2)		X
Polyomavirus		X

All rat colonies are tested at least quarterly for the following infectious agents:

Rat Panel Tests	Rat Basic	Rat Comprehensive

Rat coronavirus/Sialodacryoadenitis (RCV/SDAV)	X	X
NS1(generic Parvovirus)	X	X
Rat Parvovirus (RPV)	X	X
Rat Minute Virus (RMV)	X	X
Kilham's rat virus (KRV)	X	X
Toolan's H-1 parvovirus	X	X
Rat theilovirus (RTV)	X	X
Pneumocystis carinii	X	X
Sendai virus	X	X
Pneumonia Virus (PVM)	X	X
Mycoplama pulmonis	X	X
Reovirus type 3 (REO-3)	X	X
Lymphatic Choriomeningitis Virus (LCMV)	X	X
CARB		X
Hanta virus		X
Clostridium piliforme		X
Mouse Adenovirus 1 (MAV1)		X
Mouse Adenovirus 2 (MAV2)		X

b. Describe methods used to control, contain, or eliminate infectious agents.

Methods used to control, contain, and eliminate infectious agents include segregation of animals in rooms according to health status, the use of personal protective equipment (such as gloves, gowns, shoe covers and masks) by animal care technicians and research personnel in animal rooms.

In the event that elimination of an infectious agent is required, specific actions taken will depend on the infectious agent present and can include: rederivation, treatment (bacterial agents, fur mites, pinworms), depopulation, vermin control, and environmental decontamination.

2. Quarantine and Stabilization [*Guide*, pp. 110-111]

a. Describe the initial animal evaluation procedures for each species.

All species upon receipt are examined by the animal care staff and, if abnormalities are observed, the Managing Director and/or VMC is notified. Depending on the seriousness of the problem, the vendor may be notified and a request made for replacement of either the entire shipment or individual animals

b. Describe quarantine facilities and procedures for each species. For each species, indicate whether these practices are used for purpose-bred animals, random-source animals, or both.

Purpose bred species including rodents are quarantined (in order to acclimate) in their definitive animal holding rooms for at least 48 hours prior to their use

(b)(6) does not have a designated holding room for quarantine, however if we need to quarantine a group of animals, a room will be made available.(b)(6) has a designated quarantine,(b)(6) We typically don't have a need to quarantine because of our strict screening policy on animal health status.

c. Describe the required/recommended stabilization period for each species.

Typically, animals are recommended an acclimation period of 48 hours before use. Exceptions to the standard 48-hour acclimation period must be scientifically justified in the protocol and approved by the IACUC. The length of time for stabilization depends on the type and duration of animal transportation, the species involved, and the intended use of the animals.

3. Separation by Health Status and Species [*Guide*, pp. 111-112]

a. Describe the program for the separation of animals by species, source, and health status. If the animals in different status are not maintained separately, describe circumstances in which mixing occurs and explain the rationale for mixing.

a) Species: Only animals of the same species are housed in a room together.
b) Source: Animals used in a single study are purchased from the same source.
c) Health status: Only animals (rodents) with the same health status are housed together.

b. Describe situations where multiple species may be housed in the same room, area, or enclosure.

We do not allow multiple species to be housed in the same room.

c. Describe isolation procedures and related facilities for animals.

Animals that become ill are maintained in their housing room but isolated to the extent possible from the rest of the animals may be at the facility, room, or primary enclosure level. Under the supervision of the VMC, all infected animals are either isolated and treated, culled or rederived.

C. Clinical Care and Management [*Guide*, pp. 112-115]

1. Surveillance, Diagnosis, Treatment and Control of Disease [*Guide*, pp. 112-113]

a. Describe the procedure(s) for daily observation of animals for illness or abnormal behavior, including:

- the observers' training for this responsibility
- method(s) for reporting observations (written or verbal)

- method(s) for ensuring that reported cases are appropriately managed in a timely manner.

Daily animal observation is performed by the animal technicians responsible for animal room care. At the beginning of the work day, the technicians inspect the respective animal rooms they are responsible for and observe the animals in that room cage-by-cage. The technicians have been trained by the Managing Director and the VMC to recognize signs of animal health abnormalities. Problems pertaining to animal health or abnormal behavior are verbally reported to the Managing Director and also outlined in writing in animal room health reports.

Once the Managing Director and VMC are informed of a sick animal as described above and the investigator concurs that the specific treatment proposed for the animal's condition will not interfere with experimental results, the VMC prescribes appropriate treatment in writing and technicians, Managing Director or the VMC administers treatment. Records of the treatment are made immediately in the individual animal's records. All treatment records are reviewed by the VMC periodically. Should medical treatment not be acceptable for the animal, the investigator is typically asked to euthanize it. The VMC has final authority on animal health.

b. Describe methods of communication between the animal care staff and veterinary staff and the researcher(s) regarding ill animals.

Upon finding an injured or sick animal, the VMU animal caretaker generates a health report and contacts the Managing Director for initial consultation. The Managing Director then contacts the VMC with a description of the problem and the VMC gives suggestions for treatment.

When an animal is found to be ill, the researcher is immediately notified by the Managing Director or Animal Care Technician (for the VMC) of the finding and what the treatment plan is. VMC discuss with researchers the tentative diagnosis, its implications to the well-being of the animal and to the research, and treatment options available. Researchers have the opportunity to decide if they want the animal treated or if it is no longer suitable for the study and can opt to euthanize. We notify directly by phone or email or in person. Once the VMC prescribes care, either the Managing Director or animal care techs carry out the treatment plan. The VMU Staff stays in close contact with all animal research staff until issue is resolved.

c. Describe the preventive medicine and health management/monitoring programs (e.g., physical examination, TB testing, vaccination, hoof/nail trimming, teeth cleaning/floating, vendor surveillance, use of sentinel animals) for each species.

In the instances of rodents, the VMU relies on vendor surveillance to ensure proper health. Records of vendor surveillance are reviewed by VMC when provided with each animal order. Health surveillance records of rodents from other non-approved vendor sources (i.e. universities) are required before admittance of the animals into the facility.

Sentinel animals are placed in all rodent rooms for 3-month intervals. Two mice or one rat are used for each principle investigator's colony or on each rack or room. Dirty bedding is added from random cages in the room during cage change outs to improve potential for detecting infectious agents in the room. Sera from rodents are collected and examined quarterly for titers to pathogenic organisms by a diagnostic laboratory via either serological evaluation or by the new OptiSpot system (IDEXX BioAnalytics). Histologic and parasitological examination is performed by the VMC. Any sick animal may also be used for health monitoring if needed during the year.

2. Emergency Care [*Guide*, p. 114]

a. Describe the procedures to ensure that emergency veterinary care is continuously available for animals during and outside of regular work hours, including access to drugs or other therapeutics and equipment.

Veterinary care is provided 24 hours per day, 365 days per year. The VMC is on-call after-hours. Any health problem noted by any animal user at any time, including evenings, weekends and holidays, is reported promptly to the VMC. A listing of the home and cell phone numbers of the VMC, the Managing Director and all animal care staff members is provided should emergencies arise within the animal facility during nights, weekends or holidays. This list is available to each VMU staff member, the boiler plant and research office staff. All animal user's names and contact phone numbers are posted by the room doors. They are notified of any emergency situations. If they are unavailable, the VMC has the authority to make the decision to treat the animal, remove it from the study or to euthanize if necessary.

b. Describe the authority of the Attending Veterinarian or his/her designee relative to the emergency treatment of animals in the program.

When a situation arises, we first try to contact the lab with the description of the problem and recommendations on how to treat the situation. If the lab is not available or we cannot contact them, the veterinarian (or his designee, i.e. Managing Director or animal tech) will assess the situation, relay it to the VMC and ultimately the VMC has the authority to treat, remove from experiment, or euthanize if necessary.

3. Clinical Record Keeping [*Guide*, p. 115]

a. Describe the procedure for maintaining medical records and documenting treatment of ill animals including: clinical laboratory findings, diagnoses, treatments, medical progress records, etc. Identify the species for which individual records are maintained and where such records are kept.

Information regarding changes in animal health status, including the results of physical examinations, clinical laboratory findings, and probable diagnosis and treatment rendered are recorded in monthly VMC reports to the IACUC. Serology records are kept electronically as well as with IDEXX. These records are maintained in the Managing Director's office.

For sick animals, health records remain with the animal until the condition resolves. The records are then maintained by the Managing Director. In some instances (i.e. surgical records) individual investigators will maintain their own records which are kept with the animals, in the wall desk, for the duration of the study. Once the study is concluded, the investigator maintains the records.

b. Identify individual(s) (titles, not necessarily names) responsible for maintaining such records and identify where the records are maintained and who, including the IACUC/OB has access to the records.

All health report records are kept on file by the Managing Director. Serology results are kept electronically. The records are accessible to the Researchers and IACUC member upon request.

c. Describe the role of the Attending Veterinarian in recordkeeping.

The AV/VMC signs off on all health reports that require treatment or monitoring. If only monitoring of the animal is required, the vet staff can make notes and sign the reports as well. Once the case is closed, the files are kept by the Managing Director.

4. Diagnostic Resources. Describe available diagnostic methods used in the program including:

a. In-house diagnostic laboratory capabilities.

None

b. Commercially provided diagnostic laboratory services.

Research Service utilizes the diagnostic laboratories of the IDEXX BioAnalytics on a quarterly basis to define the rodent viral profiles necessary as a component of the sentinel animal health surveillance program. Three quarters out of the year we submit sample and have the Basic Mouse and rat serology profiles ran and once a year we have the Comprehensive profile analyzed.

c. Necropsy facilities and histopathology capabilities.

The VMU has a necropsy work station located in (b)(6), (b)(6) and in (b)(6) In addition, the CVAMC occasionally schedules necropsies to be performed in house, by the VMC for the identification of specific problems.

The VMU has a histology lab, run by the Managing Director of the VMU. (b)(6), (b)(6). Services such as paraffin embedding, sectioning, H&E staining are available.

d. Radiology and other imaging capabilities.

Our VMU and scientific programs have only infrequent requirements for radiology services. When needed, such services can be contracted for either a local Veterinary Hospital, CCHMC, or at the UC LAMS.

5. Drug Storage and Control

a. Describe the purchase and storage of controlled and non-controlled drugs.

Purchase of Controlled Substances:

1. Research service sends an email to pharmacy service requesting the drug. If the order is to be procured through the prime vendor, the pharmacy procurement technician enters the order using the Controlled Substance Ordering System (CSOS) which is then signed by one of the designated pharmacists. If the order is not from the prime vendor, either a DEA 222 form is filled out by the procurement technician and signed by the pharmacist, or a hard copy prescription is received from a licensed Research Service M.D.
2. Once orders are received, they are secured in the vault and the Accountable Officer is notified.
3. The Accountable Officer and pharmacy employee open the orders together and verify the contents against the invoice, signing and dating the invoice. The contents are added to the electronic inventory and placed into pharmacy stock.
4. Pharmacy Service will notify the principle investigator when the drugs are received. The drugs are stored in the inpatient vault until the investigator can pick them up. The authorized person must bring the Controlled Substance Administration Record (CSAR), along with proper identification to the Inpatient Pharmacy. It is the responsibility of each area to maintain appropriate stock of blank CSARs, for use by the research staff.
5. Upon receipt of the controlled substance, the authorized employee will check all drugs and verify amounts dispensed without breaking package seals.

Storage of Controlled Substances:
Controlled substances will be stored in be stored in double locked cabinets. Refrigerated narcotics must be maintained in a double locked area consistent with VHA Handbook 0710.01. We use a lock box within a refrigerator with a lock on it.

Currently, controlled drugs are stored in locked boxes available in (b)(6) (b)(6): these are subject to unannounced monthly inspections by hospital personnel overseen by the Pharmacy Service.

The controlled substance Station Memorandum for the Cincinnati VA can be found on the VA home page under policies/Cincinnati Policies/Pharmacy/document 119-02

Purchase of Non-Controlled Drugs:
Non-Controlled drugs must be purchased through VA Pharmacy Service. When they arrive, the drugs are given to the investigator or lab staff directly.

Storage of Non-Controlled Drugs:
Non-controlled drugs can be stored in an unsecured location within the lab or in the VMU. Care should be taken to watch the expiration dates and dispose of expired drugs accordingly. No expired drugs may be used in animals.

b. Describe record keeping procedures for controlled substances.

Pharmacy will transfer the research controlled substance to the "research service" vault and provide the drug, accompanied by VA Form 10-2638 to the PI or Designated Provider.

1. Upon receipt of the controlled substance, the PI or Designated provider will check all drugs and verify amounts dispensed without breaking package seals.
2. After verification:
    a) VA Form 10-2638 will be signed by the Designated Provider or designee and the Pharmacy Employee dispensing the controlled substance.
    b) Documentation of administration of controlled substances will be made on Form 10-2638 by research personnel and must indicate the protocol number, date, and any other identifying information available to provide a satisfactory proof of use record for each dose of drug administered.
    c) When the supply of medication is exhausted or it is deemed the controlled substance is no longer needed in the research area, the completed VA Form 10-2638, along with any drug being returned, will be returned to the Pharmacy. The pharmacy employee, prior to filing the form, must review the completed form for arithmetic errors, losses, or unusual waste and update the entry in the Vista Controlled Substance package to denote completion.
    d) When supply of medication is exhausted the completed green sheet must be returned to pharmacy within 72 hours.

Records are filed in Pharmacy Service per Pharmacy Records Schedule.

D. Surgery [*Guide*, pp. 115-123]

1. Pre-Surgical Planning [*Guide*, p. 116]

Describe the process(es) used to ensure adequate pre-surgical planning, including: identifying personnel; locating equipment, supplies, veterinary involvement for selecting analgesic and anesthetic agents and facilities; planning; and pre- and post-operative care.

AV/VMC, in conjunction with the investigative team, analyzes for the suitable equipment and supplies for initiation of a protocol. During ACORP pre-review, the VMC discusses with the PI or designee regarding anesthetics and analgesics, intra- and post-operative monitoring, potential complications, and training needs. The IACUC and/or the AV may require researchers to demonstrate proficiency. If required, hands-on training is provided. The investigative team is responsible on the day to day basis to provide all necessary supplies for their surgeries.

All investigators are responsible for maintaining their own records of intra-operative and perioperative procedures. Records are kept in the animal housing rooms for the duration of the study and then in the laboratories of the investigators once the project has concluded (rats, mice).

2. **Surgical Facilities** [*Guide*, pp. 116-117, 144-145]
List building name(s) and room number(s) or other locations (coded, if confidential) where surgical procedures are performed. For each, describe:
   - the type of species (including rodents, fish, agricultural species, etc.)
   - nature of procedure(s) (major/minor/emergency, survival and non-survival, etc.)
   - the amount of use [heavy (daily), moderate (weekly), or light]
   - major surgical support equipment available (gas anesthesia machines, respirators, surgical lights, etc.)
   - facilities for aseptic surgery, surgical support, animal preparation, surgeon's scrub, operating room, and postoperative recovery
   - construction features of the operating room(s), including interior surfaces, ventilation, lighting, and fixed equipment used to support surgical procedures and other means of enhancing contamination control

Note: If preferred, the information requested in this section may be provided in Table.

(b)(6) is a shared procedure room that can be used as a rodent aseptic survival or non-survival surgical area. The surgical table must be cleaned and disinfected prior to aseptic surgery. In some cases, surgeries on rodents are performed within the biosafety cabinet in the animal holding room. The area is prepared accordingly for surgical use. (b)(6) – We have an "Anesthesia Equipment" brand, rodent anesthesia (isoflurane) machine available for use. We also provide for use, heating pads, restraint tubes for injections, a hot bead sterilizer and surgical lights.

(b)(6) is the pig surgery room. This area is used for both survival and non-survival swine surgeries (no current swine protocols). There is a scrub room prior to entry. (b)(6) - Physiologic monitoring equipment includes: Instrumentation

Laboratories Gem Premier 3000 Blood Gas, pH, Hematocrit Analyzer, Columbus Instruments BP-2 Blood Pressure Monitor with blood pressure transducers and computer; Bovie Aaron Medical Electrocautery Unit, Wild Operating Microscope, Braintree Scientific Infusion Syringe Pump BS-300; Sage Instruments 341A Syringe Pump; YSI 4000A Precision Electronic Thermometer; Operating Table, Respirator, Heating pad and portable heater to help control body temperature.

(b)(6) is a rodent surgery suite within the Procedure (b)(6) equipped with a surgical light, stainless steel counter tops and exhaust snorkel as well as a portable anesthesia machine.

(b)(6) receive light to moderate use and (b)(6) is not in use at this time.

3. **Surgical Procedures** [*Guide*, pp. 117-118]

a. Describe the criteria used to differentiate major from minor survival surgery, including classification for certain procedures (e.g., laparoscopic technique).

Major survival surgery is defined as a surgical procedure that penetrates and exposes a body cavity, produces substantial impairment of physical or physiologic function, or involves extensive tissue dissection or transection.

b. How is non-survival surgery defined?

Any surgical procedure conducted under a surgical plane of anesthesia where an experimental manipulation or data collection is performed prior to the animal being euthanized while still under anesthesia.

4. **Aseptic Technique** [*Guide*, pp. 118-119]

a. Describe procedures, equipment, and protective clothing used for aseptic surgery. Include patient and surgeon preparation.

All equipment that will be in the surgical field is sterilized prior to use. The animals are prepared by clipping the hair at incision site and scrubbing the area with alternate scrubs of betadine/chlorhexidine and 70% alcohol repeated 3 times, and draping the animal to prevent contamination. Hair removal is performed in an area separate from the surgical area. The surgeon has to wash with soap and dry their hands before aseptically donning sterile surgical gloves. The surgical scrub of the surgeon(s) (in large animal surgery) is a standard scrub of 5 minutes using a povidone iodine or chlorhexidine based antiseptic surgical scrub. Clean lab coat or surgical scrubs, sterile gloves, surgical masks, and bonnet is always required for sterile surgical procedures. Sterile surgical gowns are required for non-rodent USDA-covered species (if applicable). In larger animals draping of the surgical field with sterile surgical drapes is required, while in smaller animals it is recommended.

b. Describe methods used to sterilize instruments and protective clothing, including a description of approved liquid sterilants and instrument exposure time(s) required for each, if applicable.

Instruments and clothing are washed, wrapped and steam sterilized. Gas sterilization is available if necessary through Supply Processing and Distribution (SPD). Effective sterilization is monitored by using autoclave tape that changes color upon reaching sterile temperature.

c. Describe methods for instrument re-sterilization between serial surgeries.

On rodents not USDA-covered species, between animals, instruments are sterilized using a glass bead sterilizer.

d. Indicate how effectiveness of sterilization is monitored.

Researchers: Effectiveness of sterilization is via the use of steam indicator tape, indicators on sterilization pouches, or OK sterilization strips. To monitor sterility, each pack is prepared with an indicator strip and sterilization tape appropriate for the sterilization method used.

e. Describe surgical support functions provided by the program to investigators.

The facility does not have a dedicated surgical team, thus all teams are self-reliant for procedures. However, if requested VMC can assist with any surgical procedures. In addition, isoflurane anesthesia systems are available for use and managed by the VMU.

5. Intraoperative Monitoring [*Guide*, p. 119]
Describe monitoring and recording requirements for each species, including the type of record(s) maintained. Also note monitoring of anesthesia during non-survival procedures.

Administration of anesthetics and analgesics is recorded in surgery records maintained by research personnel. Monitoring parameters include lack of reflex responses (e.g., pedal withdrawal, palpebral/corneal), assessment of respiratory rate and depth, body temperature, and muscle relaxation. Animal Surgical Health Reports (anesthesia, analgesia, surgery) are typically maintained for the life of the animal or 3 years beyond the disposition date (USDA-covered rodents). Animal Surgical Health Report contains date, surgeon, animal ID#, pre-surgical body weight, anesthetics, analgesics, time of all anesthetic monitoring, surgical activities, and post-op observations.

For non-survival procedures where the animal is under anesthesia, the same monitoring applies to ensure the expected outcome of the procedure.

6. **Postoperative Care** [*Guide*, pp. 119-120]
Describe the postoperative care program, including who is responsible for overseeing and providing the care, types of records maintained (e.g., perioperative), where the records are maintained, etc.

Following surgery, animals are continuously monitored until recovered from anesthesia. Research personnel administers post-operative analgesics and provides post-operative monitoring and care in accordance with the approved ACROP. Animal Surgical Health Reports are duly completed and maintained by research personnel. The Animal Surgical Health Report contains the following postoperative information: date, time, surgical site, animal condition, analgesic/treatment, and the suture/staple removal date. Daily monitoring by research personnel continues until the animal is recovered and no longer requires analgesics. In addition, VMU husbandry staff monitors all animals daily and pays particular attention to post-op animals.

After anesthetic recovery, monitoring is often less intense but includes attention to basic biologic functions of intake and elimination and behavioral signs of postoperative pain, monitoring for postsurgical infections, monitoring of the surgical incision, bandaging as appropriate, and timely removal of skin sutures, clips, or staples.

E. Pain and Distress [*Guide*, pp. 120-121]

1. Describe how and by whom pain and distress are assessed.

The ACORP review process includes assigning an appropriate pain class based on the anticipated pain and/or distress during experimental manipulation(s). All personnel working with animals are trained to recognize normal and abnormal species-typical behaviors to ensure pain and/or distress is minimized. Monitoring of pain and/or distress is done primarily by research personnel, who commonly are the individuals administering the analgesics. VMU husbandry staff performs health monitoring rounds daily on all animals housed in the vivarium. If any animal is noted to be in pain and/or distress be reported to VMC through Managing Director of VMU and the animal immediately evaluated by either Managing Director or veterinarian.

2. Describe training programs for personnel responsible for monitoring animal well-being, including species-specific behavioral manifestations as indicators of pain and distress.

VMU husbandry staff are trained to recognize signs of animal health abnormalities such as acute pain vs chronic pain from species to species, and within a species as it relates to individual, sex, and age differences. Staff training is an ongoing exercise (e.g., refresher training) to keep staff current on updates in knowledge, practices, and, most importantly, to recognize early signs of pain and distress in novel and new experimental models. Additional resources (e.g., AALAS training manuals, books, CE classes, and online courses) are available to support the training for the species-specific recognition of pain and distress. Research staff is trained during initial IACUC orientation, VMU access orientation, and species-specific training. Additional training is provided if requested or if animal welfare or compliance concerns arise.

F. Anesthesia and Analgesia [*Guide*, pp. 121-123]

1. List the agents used for each species.
Note: If preferred, this information may be provided in Table or additional Appendix.

Mouse	Anesthetic	Ketamine/Xylazine Ketamine/Xylazine/Acepromazine Isoflurane Telazol
	Analgesic	Buprenorphine Meloxicam Carprofen Bupivacaine
Rat	Anesthetic	Ketamine/Xylazine Ketamine/Xylazine/Acepromazine Inactin Isoflurane Sevoflurane Pentobarbital sodium
	Analgesic	Buprenorphine Meloxicam

2. Describe how the veterinarian provides guidance and advice to researchers concerning choice and use of anesthetics, analgesics or other pain moderating methods.

As part of the ACORP veterinary pre-review process, VMC advises the PI on the selection of anesthetics (injectable vs inhalation), analgesics (opioids, nonsteroidal anti-inflammatory agents, local anesthetics) and other pain moderating methods based on the species being used and the procedure being performed. In addition, Research personnel can contact VMC at any time to discuss anesthetic/analgesic regimens. If there is evidence that the anesthetic and/or analgesic regimen selected is inadequate, the VMC will work with the researcher to make the needed refinements in order to enhance the well-being of the animals. Modifications are submitted to the IACUC for review and approval.

3. Describe the monitoring of the effectiveness of analgesics, including who does the monitoring. Include in the description any non-pharmacologic means used to diminish pain and distress.

The effectiveness of anesthetics and analgesics is assessed by trained research personnel. Post-surgical care and monitoring (including effectiveness of analgesics) are provided by research personnel. Daily assessment by research personnel continues until the animal is recovered and no longer requires analgesics. In addition, VMU husbandry staff monitors all animals daily and pays particular attention to animals that have Animal Surgical Health Report. Any evidence of pain or distress is reported to veterinarian through Managing Director of VMU. The veterinarian will evaluate the animal and discuss options with the PI (e.g., administration of additional or alternative analgesics, euthanasia).

For new procedures, the IACUC may require veterinarian to be involved initially to ensure efficacy of anesthetics and analgesics used.

4. Describe how the veterinarian(s) and the IACUC/OB evaluate the proposed use of neuromuscular blocking agent to ensure the well-being of the animal.

We do not have any proposals for the use of Neuromuscular blocking agents. The use of neuromuscular blocking agents is strongly discouraged. Its use must be scientifically justified in the IACUC protocol and must include a detailed description of how the depth of anesthesia will be assessed (e.g., EEG, heart rate and/or blood pressure trends).

5. Describe policies and practices for maintaining and ensuring function of equipment used for anesthesia.

Each F/Air canister used to collect waste gases is dated and the average useful life of each canister is estimated to be approximately 12-15 hours of use. Once the canister reaches 50 grams (small) or 100 grams (large) above starting weight, it is discarded and replaced. If the canister does not reach 50 grams above starting weight by 6 months, it is replaced to help ensure the activated charcoal does not dry out leading to diminished scavenging capacity. Oxygen cylinders are checked prior to each use to ensure there is an adequate supply of oxygen available. All gas anesthesia machines that are in use are serviced biannually by an authorized vendor.
PI-owned rodent anesthesia equipment: The same recommendations apply with regard to routine maintenance of gas anesthesia machine. Servicing of equipment by an authorized vendor is done at least once every 2 years.

G. Euthanasia [*Guide*, pp. 123-124]

1. Describe approved methods of euthanasia, including humane slaughter (for additional guidance, see pertinent AAALAC Reference Resources). Include:
    - consideration of species, age, condition (e.g., gestational period, or neonatal) and
    - location(s) for the conduct of the procedure.

Note: If preferred, this information may be provided in Table or additional Appendix.

All methods of euthanasia are supported by the AMVA Guidelines for the Euthanasia of Animals: 2013 Edition unless scientifically justified and approved by the IACUC. The following are common methods employed:
Mice: injectable barbiturate overdose, CO_2 overdose, cervical dislocation with or without anesthesia, decapitation with or without anesthesia, inhalant anesthetic overdose, injectable anesthetic overdose (Tribromoethanol), and perfusion under anesthesia.

Rats: injectable barbiturate overdose, CO_2 overdose, decapitation with our without anesthesia, inhalant anesthetic overdose, inhalant anesthetic overdose followed by exsanguination, injectable anesthetic overdose, perfusion under anesthesia.

Hamsters: CO2 overdose, exsanguination under anesthesia.

For mice and rats 6 days of age or younger, hypothermia followed by a physical method (e.g., decapitation) may be performed. Decapitation or cervical dislocation in conscious rodents (e.g., mice, rats) is acceptable with conditions (per AVMA).

Locations: Animals are euthanized in VMU procedure/necropsy rooms. Animals exposed to hazardous agents and rodents in quarantine rooms may be euthanized within the animal housing room due to OHS and biosecurity concerns.

2. Describe policies and practices for maintaining and ensuring function of equipment used for euthanasia.

CO_2 overdose – CO_2 euthanasia systems include flow meters and pressure regulators which are preset for appropriate CO_2 gas output. VMU CO_2 euthanasia systems are checked daily to ensure proper function.

Inhalant anesthetic overdose – Inhalant anesthetic overdose can be performed using a precision vaporizer or a drop box method within a chemical fume hood. Anesthesia machine maintenance has been previously discussed. Fume hoods are inspected and certified annually.

Physical method – Equipment used to perform physical euthanasia (e.g. guillotines, sharp scissors) must be maintained and serviced regularly to be in appropriate operating condition at all times. Maintenance logs or service work orders are reviewed during IACUC semiannual inspections and PAM visits.

(See SOP Maintenance of Decapitator VMU 023), available on site.

3. Describe the methods used to confirm death of an animal.

Death is confirmed by cessation of breathing, absence of a heartbeat, and negative corneal reflex. A secondary method to confirm death must be used when the primary method involves the use of chemical agents (e.g., CO_2, inhalant anesthetic overdose, and injectable anesthetic overdose). The following physical methods are used depending on species: cervical dislocation, decapitation, bilateral pneumothorax or cutting of the diaphragm, removal of a vital organ, and perfusion with fixative.

IV. Physical Plant [*Guide*, pp. 133-155]

A. Facilities Overview

Provide a brief introduction to the animal housing and use facilities. Note that this overview should augment the information provided in **Appendix 2** (Summary of Animal Housing and Support Sites), which includes area, average daily census, and person responsible for each site. Please use consistent terminology for the buildings/areas/sites described in the Location section of the Appendix. Please do not repeat information, but supplement the descriptions provided elsewhere to assist the reviewers understanding of the interaction between facilities, special housing locations, and separate procedural areas.

The VMU of the CVAMC is located on the first floor of (b)(6) adjoining the main hospital (b)(6) to the (b)(6) as well as our new facility, (b)(6) which is attached to the (b)(6 side of (b)(6) Total square feet of (b)(6) = 4890. Total net square feet of animal rooms is 2010. Total square feet of (b)(6) VMU = 7,600; Including a total of 1600square feet in the animal rooms and 6,000 square feet of support space. The average daily census (Based on FY 18 census) between all VMU space is approximately 348 mice and 41 rats.

The program is immediately overseen by the Managing Director of the VMU and the VMC along with the staff of one full time and 2 part-time animal care technicians.

B. Centralized (Centrally-Managed) Animal Facility(ies)

In this section, describe each centralized or centrally-managed animal housing and use facility. Include in **Appendix 3** the floor plans of each on 8.5" x 11" or A4 paper. Ensure that the drawings are legible and the use of each room is indicated (animal housing, procedure room, clean cage storage, hazardous waste storage, etc.). Note that a separate section for describing "satellite housing areas" is included below.

Separately describe **each** Location or Animal Facility, addressing each of the features outlined below (1-8). A complete description of each must be provided; however, common features among locations or facilities may be indicated as such and do not need to be repeated.

1. General arrangement of the animal facilities (conventional, clean/dirty corridor, etc.).
2. Physical relationship of the animal facilities to the research laboratories where animals may be used.

3. Types of available animal housing spaces used, such as conventional, barrier, isolation/quarantine, hazard containment (infectious, radioactive, chemical), "animal cubicles" or facilities specifically designed for housing certain species such as ponds, pastures, feedlots, etc.
4. Finishes used throughout the animal facility for floors, walls, ceilings, doors, alleyways, gates, etc. (note any areas that are not easily sanitized and describe how these are maintained).
5. Engineering features (design, layout, special HVAC systems, noting exhaust air treatment, if applicable) used in hazardous agent containment.
6. Security features, such as control of entry, perimeter fences, gates, entryways, cameras, guards; identify and describe exceptions for individual facilities or areas incorporating fewer or additional security features than the general features described.
7. Consideration for facilities with exterior windows, if applicable, including management of environmental conditions (i.e., temperature and photoperiod control) and potential security risks.
8. Storage areas for flammable or hazardous agents and materials (e.g., disinfectants, cage-washing chemicals, pesticides, fuel).

(b)(6) – The facility has been designed to have a dirty and clean side. All clean animal rooms are located along one hallway. There is also the clean side autoclave unloading (b)(6 (b)(6) where autoclaved feed, bedding and enrichment are stored, as well as a "clean" procedure room (b)(6) for survival procedures. Clean cages and racks enter from one hallway into these areas. Dirty cages are taken through a second corridor to the "dirty" side of the facility. Cages are dumped in a dedicated cage dumping room ((b)(6) Cages come out of the rack washer, and mouse cages are then bedded and sterilized before going back to the clean side of the facility, whereas rat cages are bedded with autoclaved bedding upon coming out of the rack washer on the clean side. All bedding, food and water bottles (for designated studies) are also passed through the sterilizer before going to the clean side of the facility. Racks pass through the rack washer directly to the clean side of the facility through the back door of the rack washer. We have one room designated as an ABSL-2 housing room, with an exhaust heap-filter on the PIV rack. The pig housing area and necropsy room are in what is considered the dirty area. For security, (b)(6) is equipped with a card reader entry system which requires a PIN code with a VA police issued badge to gain entry. There is also an audible alarm system with motion detectors that is enabled after hours. All chemicals used in the facility are stored according to VA guidelines. We have flammable cabinets for use as well as catch basins for all cage washing and cleaning chemicals.

(b)(6) – This is a newly constructed building since our last AAALAC site visit. We have not been using the facility long. This facility was designed as a "clean" facility and there is only one hallway of animal rooms which contain both PIV and conventional housing. There is one holding room for quarantine and one that can be used for larger animals or aquatics if the need arises. It has floor flushing drains incorporated into it (b)(6) also contains a Necropsy/Histology (b)(6) a procedure room with a small animal surgery suite, a feed and bedding storage room, a house-run CO2 system, loading dock and an animal RO watering system. There is a clean and dirty cage wash (b)(6) with all machines being pass through. There is a bulk sterilizer, a double length custom cage washer and a small bottle washer. Cages are dumped on the dirty side in a down draft dump station. As i(b)(6) all mouse cages are autoclaved and rat cages are bedded with autoclaved bedding. For security, (b)(6) is equipped with the PIN coded card reader entry system as well as security cameras that can be monitored from the police office. There is also a security gate behind the building so no vehicles can pull directly up to the building unless we allow it. We have flammable cabinets for use as well as catch basins for all cage washing and cleaning chemicals.

Both VMU facilities are equipped with the Edstrom Watchdog watering system and environmental monitoring system. (b)(6) runs water though a filter bank an(b)(6) has both and RO system and a back-up filter system. Both facilities are monitored for temperature and humidity and (b)(6) has light controls.

All bench research laboratories are located on the 2nd through (b)(6) above the(b)(6) animal holding areas, o(b)(6). There are also research laboratories in (b)(6) n the (b)(6) which is accessible by an enclosed walkway connecting the 2 buildings on th(b)(and (b)(6) The labs in building one are currently not occupied.

Animal Room Doors – are constructed of painted steel in(b)(6) nd a resinous material i(b)(6) with metal or stainless steel door frames.

Floors – (b)(6) f the animal facility are constructed of concrete covered by epoxy resin and some have quartz/resin floors(b)(6) as epoxy resin flake broadcast flooring over concrete throughout, with an industrial coating in the cage wash areas. All entry and exit paths in(b)(6) lso have Techtrak flooring for contamination control.

Walls – All walls in both buildings of the animal facility are constructed of epoxy painted concrete masonry block, with the exception of one wall of the clean hallway o(b)(6) which is painted drywall. All walls are in good to excellent condition.

Ceilings – All ceilings are either drywall or waterproof lay-in. Ceilings are in good to excellent condition.

C. Satellite Animal Housing Facilities

In addition to the Appendices summarizing Heating, Ventilation, and Air-Conditioning (**Appendix 11**) and Lighting Systems (**Appendix 16**), summarize animal housing areas that are not centrally-managed or maintained in (**Appendix 17**), "Satellite Animal Housing Areas."

1. Describe the criteria used to determine/define a "Satellite Animal Housing Area," which may include remote housing facilities or laboratories temporarily or consistently housing animals.

We do not have any satellite housing areas at this time.

2. Describe the process used by the IACUC/OB to authorize, provide oversight of, and ensure compliance with *Guide* standards for the housing of animals outside of centrally-maintained facilities. Include a description of Attending Veterinarian access and physical security.

Not Applicable

D. Emergency Power and Life Support Systems

Note: Complete a Heating, Ventilation, and Air-Conditioning (HVAC) Summary (**Appendix 11**) and Lighting Summary (**Appendix 16**) for each Location described in the Summary of Animal Housing and Support Sites (**Appendix 2**).

1. **Power** [*Guide*, p. 141]
For each Location, Centralized Animal Facility, and Satellite Housing Facility, provide a brief description of the following:
   - Availability of emergency power and if so, what electrical services and equipment are maintained in the event the primary power source fails.
   - History of power failures, noting frequency, duration, and, if emergency power was not available, steps taken to ensure the comfort and well-being of the animals present and the temperature extremes reached in animal rooms during the failure.

Power supply to (b)(6) is provided by 2 main electrical feeders. The first is our preferred feeder. The second is our alternate feeder. If power is lost from one, we automatically switch to the other. For (b)(6) only an emergency lighting generator will start only if a total power failure was to occur, all other power will be lost.

Power to Building 14 is provided by the same 2 campus feeds as 15. In addition (b)(6) (b has normal and emergency power feeding the building. Nearly all lighting, power, and equipment within the building is on emergency power.

The Medical Center experienced a total power failure on June 3rd, 2015. The animal rooms maintained temps between 68 °F and 74.1°F. The power was back on within 6 hours. There were no animal deaths or complications as a result of the power outage.

Other power outages that occurred at the CVAMC:

- On March 7th at 1:35 am and on March 8th at 1:40 pm. Both of these outages were momentary and there were no complications as a result.
- Oct 6th, 2018 was a planned outage, only for a short time, no temperatures went out of range
- Oct 10th, 2018 there was a brief power outage when the generator was being tested, lost all power for just a few seconds

- Oct 17th, 2018 another brief outage when the generator was being tested, went out twice for just a few seconds.

Power outage reports are available on site.

2. **Other System Malfunctions.** If not previously reported, describe animal losses or health problems resulting from power, HVAC, or other life support system (e.g., individually ventilated cages) failures, and mechanisms for reporting such incidences. AAALAC International Rules of Accreditation (Section 2.f).

N/A

E. Other Facilities [*Guide*, pp. 144, 150]

1. **Other Animal Use Facilities** [*Guide*, pp. 146-150]
Describe other facilities such as imaging, irradiation, and core/shared behavioral laboratories or rooms. Include a description of decontamination and methods for preventing cross-contamination in multi-species facilities.

We currently have 2 animal behavior rooms set up within the (b)(6) facility. These are currently only used by one PI, using rats but it could be shared if needed. All behavior equipment is hand washed or sanitized. ATP test swabs can be run for cleaning monitoring.

2. **Other Animal Program Support Facilities**
Describe other facilities providing animal care and use support, such as feedmills, diagnostic laboratories, abattoirs, etc.

None

According to the privacy principles on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, we wish to advise you that the personal data in the Program Description will become part a permanent file owned by AAALAC International, and that can be shared with AAALAC International offices and representatives in order to perform an evaluation of the institution's animal care and use program and provide accreditation services. The institution has the option of exercising rights of data access, rectification, cancellation, and opposition at: accredit@aaalac.org

Appendix 1: Glossary of Abbreviations and Acronyms

Please provide a Table defining abbreviations and acronyms used in this Program Description.

Abbreviation/Acronym	Definition
ACOS/R	Assistant Chief of Staff for Research
ACORP	Animal Component of Research Protocol
APHIS	Animal and Plant Health Inspection Service (of USDA)
AO/R	Administrative Officer for Research
AV	Attending Veterinarian
AWR	Animal Welfare Regulations
BSO	Biosafety Officer
CCHMC	Cincinnati Children's Hospital Medical Center
CVAMC	Cincinnati Veterans Affairs Medical Center
CVMO	Chief Veterinary Medical Officer
DMR	Designated Member Review
DOD	Department of Defense
EH	Employee Health
FCR	Full Committee Review
FOIA	Freedom of Information Act
IACUC	Institutional Animal Care and Use Committee
IH&S	Industrial Hygiene and Safety
Guide or The Guide	Guide for the Care and Use of Laboratory Animals
IO	Institutional Official
MCD	Medical Center Director
MOU	Memorandum of Understanding
NIH	National Institutes of Health
OHSP	Occupational Health and Safety Program
PI	Principle Investigator
RCO	Research Compliance Officer
R&DC	Research and Development Committee
RO	Reverse Osmosis
RSO	Research Safety Officer
SOP	Standard Operating Procedure
SRS/IBC	Subcommittee on Research Safety/Institutional Biosafety Committee
TMS	Talent Management System
UC	University of Cincinnati

Appendix 1: Glossary of Abbreviations and Acronyms

Abbreviation/Acronym	Definition
UC LAMS	University of Cincinnati Laboratory Animal Medical Service
VA	Veterans Affairs
VMC	Veterinary Medical Consultant
VMU	Veterinary Medical Unit
VMU Supervisor/ Managing Director	Manager of the Veterinary Medical Unit

Appendix 2: Summary of Animal Housing and Support Sites

Briefly summarize in the following Table the animal facility or facilities, noting the number of areas in which animals are housed (buildings, floors, farms, satellite housing facilities, etc.), the total square footage/metres (or acreage) for animal care and use, and the total square footage/metres (or acreage) for necessary support of the animal care and use program covered by this Description (water treatment plant/area if housing aquatic or amphibian species, cagewashing facilities, service corridors, etc. and additional areas to be considered are enumerated in the *Guide*). Detailed information for satellite housing facilities is requested in Appendix 17. Include only one line entry for satellite housing facilities in this table to provide the total square footage for all satellite housing areas listed in appendix 17. If more than one facility/site, note the approximate distance (yards/miles or meters/kilometers) to each facility from a reference point such as from the largest animal facility. A campus/site map (with a distance scale) may be included as an additional Appendix (Appendix 2.1) to provide this information. See Instructions, Addendum A - Animal Facility Square Footage/Meters Compilation Form for guidance in calculating the size of your animal care and use program.

Animal Housing and Support Sites						
Location (building, site, farm name, etc.[a])	**Distance from main facility[b]**	**Approx. ft², m², or acreage for animal housing**	**Approx. ft², m², or acreage for support or procedures**	**Species housed**	**Approx. Daily Animal Census by species**	**Person in charge of site**
(b)(6)	On site	2010 sq. feet	2980 sq. feet	Mice and Rats	Mice: 348 Rats:41 Hamster: total of 36 over life of the protocol	(b)(6)
(b)(6)	On site	1,600 sq. feet	6,000 sq. feet	Mice and Rats	0	(b)(6)
Satellite Housing Facilities Total (Expand in Table 17)		N/A	N/A			

Totals:	**3,610 sq feet**	**8,980 sq feet**
Total animal housing and support space:	**12,590 ft²**	
	(please specify ft² or m²)	

[a]Please state name and/or use acronyms described in **Appendix 1** for building names, if not coded for confidentiality.

[b]Campus or site map(s) may also be provided in lieu of this information.

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Withheld pursuant to exemption

(b)(6)

of the Freedom of Information

Page 104 of 242

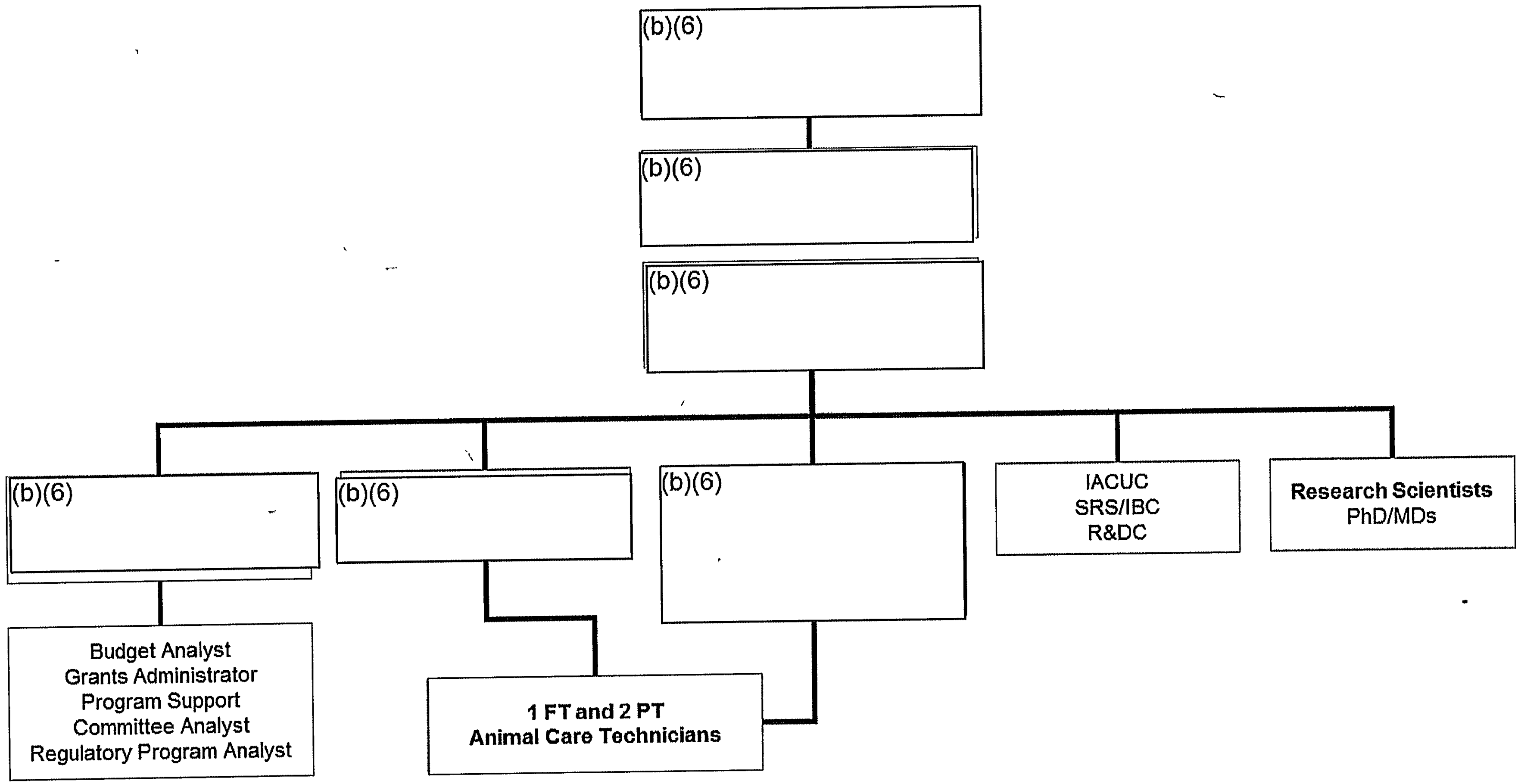
Withheld pursuant to exemption

(b)(6)

of the Freedom of Information

Appendix 4: Organizational Chart(s)

Provide an accurate, current, and detailed organization chart or charts that detail the lines of authority from the Institutional Official to the Attending Veterinarian, the IACUC/OB, and personnel providing animal care. If applicable, include personnel responsible for managing satellite housing areas/locations and depict the reporting relationship between the Attending Veterinarian and other(s) having a direct role in providing veterinary care.



Appendix 5: Animal Usage

In order to assist the site visitors in their evaluation of the animal care and use program, please provide the information requested below. Information should be provided for all animals approved for use in research, teaching or testing, including those which may be used or housed in laboratories outside the animal care facility. Of particular interest is information on those animals which are used in research projects involving recovery surgical procedures, behavioral or other testing requiring chairing or other forms of restraint, or exposure to potentially hazardous materials. An alternate format is acceptable as long as the information requested is provided.

Project/Protocol Title	IACUC/OB Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
In Vivo testing of small melanocortin analogs (pigs offsite year 4)	(b)(6)		Mouse and mini pigs	Mice – 114 Pigs - 15	D, E	√					
Babesia microti and duncani production in Hamsters			Hamster	120	D					√	
Pneumocystis pneumonia in mice			Mouse	5175	C, D, E	√				√	
Factors Influencing the Carriage and Transmission of Pneumocystis			Rat	978	C, E					√	
Tumor Suppressing Pathways in Renal Cancer (offsite)			Mouse	280	D	√				√	
Mechanisms of Liver Failure			Mouse	1033	C, D, E					√	
Neuropeptide Mechanisms and			Rat	1488	C, E	√			√	√	

Appendix 5: Animal Usage

Project/Protocol Title	IACUC/OB Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
Stress Pathologies											
Estrogen-Based combination therapies for Castration-resistant prostate cancer	(b)(6)		Mouse	851	D	√	√			√	
Immunogenetic control of autoimmune biliary disease			Mouse	1570	B, C						
Simulating Panic and PTSD relevant behaviors in mouse models			Mouse	1624	C, D, E	√			√	√	
Identification and Characterization of Chloride/ Bicarbonate Exchangers in Epithelial Tissues			Mouse	18,500	C, E					√	
Ron Receptor Signaling in Vivo			Mouse	3220	C, E	√	√			√	
Health Monitoring of Rodent Colony			Mice and Rats	Mice 480 Rats 48	C						
Holding Protocol			Mice and Rats	Mice 300 Rats 90	B						

(1) If applicable, please provide a description / definition of any pain/distress classification used within this Appendix in the space below. If pain/distress categories are not used, leave blank.

Appendix 5: Animal Usage

(2) Survival Surgery (SS)
(3) Multiple Survival Surgery (MSS)
(4) Food or Fluid Regulation (FFR)
(5) Prolonged Restraint (PR)
(6) Hazardous Agent Use (HAU)
(7) Non-Centralized Housing and/or Procedural Areas (NCA), i.e., use of live animals in any facility, room, or area that is not directly maintained or managed by the animal resources program, such as investigator laboratories, department-managed areas, teaching laboratories, etc.

Pain/Distress Classification Description/Definition, if applicable:

Category B: Includes breeders, young that cannot be used because of improper genotype or gender, and any other animals that will not have any research procedures performed on them.

Category C: Includes observational studies, most intravenous and perenteral injections of non-irritating agents, most blood collections from peripheral vessels, and the collection of cells and/or tissues from animals after euthanasia has been performed.

Category D: Includes major and minor surgery performed under anesthesia (survival and non-survival), tissue or organ collections prior to euthanasia, painful procedures performed under anesthesia (such as retro-orbital blood collection), prolonged restraint accompanied by tranquilizers or sedatives, and experiments involving infectious or other hazardous materials in animals that have provisions for immediate euthanasia if they become sick to effectively prevent pain and/or suffering. If an endpoint is used that involves significant pain or distress, consideration should be given to putting animals in category E.

Category E: Includes studies in which animals are allowed to die without intervention (e.g. LD50, mortality as and endpoint), studies that allow endpoints that are painful or stressful, addictive drug withdrawals without treatment, pain research, and noxious stimulation.

In the Table below, provide an approximate annual usage for all species:

Animal Type or Species	Approximate Annual Use
Mice (FY 18 totals)	2053
Rats (FY 18 totals)	224
Hamster (life of protocol)	36 total for 2+ years

Animal Type or Species	Approximate Annual Use

[Create additional rows by pressing TAB in the bottom-right box.]

Appendix 6: Personnel Medical Evaluation Form

Periodic Animal Exposure Questionnaire

Name: ________________________________ SS#: (Last 4)__________

Job Title:__________________Extension:___________Bldg/Room#__________

Email____________________ Phone# if not at VA____________________

1. I no longer work with animals (including animal tissues, waste, body fluids, carcasses or animal quarters) at the VAMC. **YES** **NO** (if YES, skip to #4).

2. Show any **CHANGE** in animal contact within the VAMC in the past year. Write a plus (+) for continuing contact; (++) for new animal contact; (-) for animals no longer working with.

   ______Dogs
   ______Cats
   ______Rabbits
   ______Guinea Pigs
   ______Other
   ________Pigs
   ________Sheep
   ________Rodents
   ________Nonhuman Primates

3. Check total amount of contact time with animals in the past year (include contact with animal tissues, waste, body fluids, carcasses or animal quarters):

   _______More than one hour / week
   _______One hour or less / week
   _______Other (explain)______________________________

4. List any additions or deletions of human or animal pathogens or infectious diseases you have worked with in the past year:

   Additions:____

   Deletions:____

5. List the date of your last TB screening: (TB test or TB Symptoms Checklist):______

Appendix 6: Personnel Medical Evaluation Form

6. List date of Hepatitis B, Tetanus or Rabies immunizations received this past year:

   Tetanus ___________ Rabies ___________ Hepatits B ___________

7. Circle any condition(s) you have developed over the past year:

Hay fever	Asthma
Sinusitis	Other Chronic Respiratory Infection
Allergic skin problems	Eczema

Comments:

Check symptoms you developed this past year and how often you have them:

Symptoms	Never	Monthly	Weekly	Daily
Watery, Itchy Eyes				
Runny, Stuffy Nose				
Sneezing Spells				
Frequent Dry Cough				
Wheezing In Chest				
Rash or Hives				
Shortness of Breath				
Trouble Swallowing				

9. Do animals cause the above symptoms? If so, please list the animals.

____

10. List any **NEW** pets you obtained in the past year and symptoms you have with them.

New Pets	**Symptoms**

Appendix 6: Personnel Medical Evaluation Form

11. List any medical problems, pregnancies, hospitalizations or surgeries this past year.

____

____

____

Signature of Employee: ____________________________ Date: __________

Signature of Reviewer ____________________________

Print Name ____________________________

Physical Examination: Recommended________ Not Recommended________

Appendix 7: IACUC/OB Membership Roster

CINCINNATI VETERANS AFFAIRS MEDICAL CENTER
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE ROSTER

Chairs	**Role and Affiliation (Department/Division)**
(b)(6)	
Voting Members	**Affiliation**
(b)(6)	
Alternate Voting Members	**Affiliation**
	MED-Surgery (Alternate #1)
(b)(6)	
Ex-Officio (Non- Voting) Members	**Affiliation**
(b)(6)	
Guests	**Affiliation**
(b)(6)	

Appendix 8: IACUC/OB Minutes

(b)(3):38 U.S.C. 5705

(b)(3):38 U.S.C. 5705

Appendix 8: IACUC/OB Minutes

(b)(3):38 U.S.C. 5705

[redacted]

(b)(3):38 U.S.C. 5705

[redacted]

Appendix 8: IACUC/OB Minutes

(b)(3):38 U.S.C. 5705

(b)(3):38 U.S.C. 5705

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(b)(3):38 U.S.C. 5705

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(b)(3):38 U.S.C. 5705

(b)(3):38 U.S.C. 5705

Appendix 8: IACUC/OB Minutes

(b)(3):38 U.S.C. 5705

(b)(3):38 U.S.C. 5705

Appendix 8: IACUC/OB Minutes

(b)(3):38 U.S.C. 5705

[redacted]

(b)(3):38 U.S.C. 5705

[redacted]

Appendix 8: IACUC/OB Minutes

(b)(3):38 U.S.C. 5705

(b)(3):38 U.S.C. 5705

Appendix 9: IACUC/OB Protocol Forms

Form 1.

ANIMAL COMPONENT OF RESEARCH PROTOCOL (ACORP)

Main Body

VERSION 4

Please see the link below for instructions on how to write your ACORP. Each section has a link for instructions (main body, and each appendix)

https://www.research.va.gov/programs/animal_research/documents.cfm

A. **ACORP Status.**

1. Full Name of Principal Investigator(s)▶
2. VA Station Name (City) and 3-Digit Station Number▶ Cincinnati (b)(
3. Protocol Title▶
4. Animal Species covered by this ACORP▶
5. Funding Source(s). Check each source that applies:

▶( ) Department of Veterans Affairs.
▶( ) US Public Health Service (e.g. NIH).
▶( ) Private or Charitable Foundation -- Identify the Foundation:
▶( ) University Intramural Funds – Identify the University and Funding Component:
▶( ) Private Company – Identify the Company:
▶( ) Other – Identify Other Source(s):

6. Related Documentation for IACUC reference.

a. If this protocol applies to a project that has already been submitted to the R&D Committee for review, identify the project:

(1) Title of project▶

(2) If approved by the R&D Committee, give the date of approval▶

b. Triennial review. If this protocol is being submitted for triennial *de novo* review, complete the following:

(1) Identify the studies described in the previously approved ACORP that have already been completed
▶

(2) Indicate the numbers of animals of each breed/strain/genotype that have already been used, and adjust the numbers shown in Item I accordingly
▶

(3) Describe any study results that have prompted changes to the protocol, and briefly summarize those changes, to guide the reviewers to the details documented in other Items below.
▶

c. List any other relevant previously approved animal use protocols (copy the lines below as needed for each protocol listed).

(1) Title of other protocol ▶
(2) IACUC approval number of other protocol ▶
Give the name of the VA station or other institution that approved it, if it was not approved by the IACUC that will review this ACORP ▶

7. Indicate the type(s) of animal use covered by this protocol (check all that apply):

▶( ) Research
▶( ) Teaching or Training
▶( ) Testing
▶( ) Breeding and colony management only; not for any specific research project
▶( ) Holding protocol (as specified by local requirements; not required by VA, PHS, or USDA)
▶( ) Other. Please specify▶

Proposal Overview

B. **Description of Relevance and Harm/Benefit Analysis.** Using non-technical (lay) language that a senior high school student would understand, briefly describe how this research project is intended to improve the health of people and/or other animals, or otherwise to serve the good of society, and explain how these benefits outweigh the pain or distress that may be caused in the animals that are to be used for this protocol.
▶

C. **Experimental Design.**

1. **Lay Summary**. Using non-technical (lay) language that a senior high school student would understand, summarize the conceptual design of the experiment in no more than one or two paragraphs.
▶

2. **Complete description of the proposed use of animals.** Use the following outline to detail the proposed use of animals.

a. **Summarize** the design of the experiment in terms of the specific groups of animals to be studied.
▶

b. **Justify the group sizes and the total numbers of animals requested.** A power analysis is

strongly encouraged; see ACORP instructions.
▶

c. **Describe each procedure** to be performed on any animal on this protocol. (Use Appendix 9 to document any of these procedures that involve "departures" from the standards in the *Guide*. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)
▶

D. **Species.** Justify the choice of species for this protocol.
▶

Personnel

E. **Current qualifications and training.** (For personnel who require further training, plans for additional training will be requested in Item F.)

1. PI

Name▶

Animal research experience ▶

Qualifications to perform specific procedures

Specific procedure(s) that the PI will perform personally	Experience with each procedure in the species described in this ACORP

2. Other research personnel (copy the lines below for each individual)

Name▶

Animal research experience ▶

Qualifications to perform specific procedures

Specific procedure(s) that this individual will perform	Experience with each procedure in the species described in this ACORP

3. VMU animal care and veterinary support staff personnel (copy the lines below for each individual)

Name▶

Qualifications to perform specific support procedures in the animals on this protocol

Specific support procedure(s) assigned to this individual	Qualifications for performing each support procedure in the species described in this ACORP (e.g., AALAS certification, experience, or completion of special training)

4. For each of the research personnel listed in items 1 and 2 above, enter the most recent completion date for each course

Name of Individual	Working with the VA IACUC	ORD web-based species specific course (Identify the species)	Any other training required locally (Identify the training)

F. **Training to be provided.** List here each procedure in Item E for which anyone is shown as "to be trained", and describe the training. For each procedure, describe the type of training to be provided, and give the name(s), qualifications, and training experience of the person(s) who will provide it. If no further training is required for anyone listed in Item E, enter "N/A"
▶

G. **Occupational Health and Safety.**

1. Complete one line in the table below for each of the personnel identified in Item E:

Name	Enrollment in OHSP		Declined optional services	Current on Interactions with OHSP? (yes/no)
	VA program	Equivalent Alternate Program – identify the program		
	( )	( )	( )	
	( )	( )	( )	
	( )	( )	( )	

2. Are there any non-routine OHSP measures that would potentially benefit, or are otherwise required for, personnel participating in or supporting this protocol?

► ( ) Yes. Describe them ►

► ( ) No.

Animals Requested

H. **Animals to be Used.** Complete the following table, listing the animals on separate lines according to any specific features that are required for the study (see ACORP Instructions, for guidance, including specific terminology recommended for the "Health Status" column):

Description (include the species and any other special features not shown elsewhere in this table)	Gender	Age/Size on Receipt	Source (e.g., Name of Vendor, Collaborator, or PI of local breeding colony)	Health Status

I. **Numbers of animals requested.** See ACORP Instructions, for descriptions of the categories and how to itemize the groups of animals.

USDA Category B

Procedures►						
Species / Experimental Group / Procedures(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category B TOTAL**

USDA Category C

Procedures▶						
Species / Experimental Group / Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category C TOTAL**

USDA Category D

Procedures▶						
Species / Experimental Group / Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category D TOTAL**

USDA Category E

Procedures▶						
Species / Experimental Group / Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category E TOTAL**

TOTALS over all Categories

Species / Experimental Group /Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**GRAND TOTAL**

J. **Management of USDA Category D procedures**. Indicate which statement below applies, and provide the information requested.

▶ ( ) This protocol does NOT include any Category D procedures.

▶ ( ) This protocol INCLUDES Category D procedures. List each Category D procedure and provide the information requested. (For surgical procedures described in Appendix 5, only identify the procedure(s) and enter "See Appendix 5 for details.)

Procedure	Monitoring (indicate the method(s) to be used, and the frequency and duration of monitoring through post-procedure recovery)	Person(s) responsible for the monitoring	Method(s) by which pain or distress will be alleviated during or after the procedure (include the dose, route, and duration of effect of any agents to be administered)

K. **Justification of Category E procedures.** Indicate which statement below applies, and provide the information requested.

► ( ) This protocol does NOT include any Category E procedures

► ( ) This protocol INCLUDES Category E procedures. Identify each Category E procedure included in this ACORP and justify scientifically why the pain or distress cannot be relieved.

►

Veterinary Care and Husbandry

L. **Veterinary Support.**

1. Identify the laboratory animal veterinarian who is responsible for ensuring that the animals on this protocol receive appropriate veterinary medical care.

   Name►
   Institutional affiliation►
   email contact►

2. Veterinary consultation during the planning of this protocol.

   Name of the laboratory animal veterinarian consulted►

   Date of the veterinary consultation (meeting date, or date of written comments provided by the veterinarian to the PI) ►

M. **Husbandry.** As a reference for the animal husbandry staff, summarize here the husbandry requirements of the animals on this protocol. (Use Appendix 6 to justify the use of any special husbandry and to detail its effects on the animals. Use Appendix 9 to document any aspects of the husbandry that involve "departures" from the standards in the *Guide*. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

1. Caging needs. Complete the table below to describe the housing that will have to be accommodated by the housing sites for this protocol:

a. Species	b. Type of housing*	c. Number of individuals per housing unit**	d. Is this housing consistent with the *Guide* and USDA regulations? (yes/no***)	e. Estimated maximum number of housing units needed at any one time

*See ACORP Instructions, for guidance on describing the type of housing needed. If animals are to be housed according to a local Standard Operating Procedure (SOP), enter "standard (see SOP)" here, and enter the SOP into the table in Item Y. If the local standard housing is not described in a SOP, enter "standard, see below" in the table and describe the standard housing here:

▶

** The *Guide* states that social animals should generally be housed in stable pairs or groups. Provide a justification if any animals will be housed singly (if species is not considered "social", then so note)

▶

***Use Appendix 9 to document "departures" from the standards in the *Guide*.

2. Enrichment. Complete the table below to indicate whether "standard" exercise and environmental enrichment will be provided to the animals on this protocol, or whether any special supplements or restrictions will be required (See ACORP Instructions, for more information on enrichment requirements. Use Appendix 9 to document any enrichments requirements that represent "departures" from the standards in the *Guide*.):

a. Species	b. Description of Enrichment*	c. Frequency

*If enrichment will be provided according to a local SOP, enter "standard (see SOP)" and enter the SOP into the table in Item Y. If the local standard enrichment is not described in a SOP, enter "standard, see below", and describe the standard species-specific enrichment here.

▶

3. Customized routine husbandry. Check all of the statements below that apply to the animals on this protocol, and provide instructions to the animal husbandry staff with regard to any customized routine husbandry needed.

▶ ( ) This ACORP INCLUDES genetically modified animals.

List each group of genetically modified animals, and describe for each any expected characteristic clinical signs or abnormal behavior related to the genotype and any customized routine husbandry required to address these. For genetic modifications that will be newly generated on or for this protocol, describe any special attention needed during routine husbandry to monitor for unexpected clinical signs or abnormal behavior that may require customized routine husbandry.

▶

▶ ( ) Devices that extend chronically through the skin WILL be implanted into some or all animals on this protocol. Describe any customized routine husbandry to be provided by animal husbandry staff to minimize the chances of chronic infection where the device(s) penetrate the skin.

▶

▶ ( ) Some or all of the animals on this protocol WILL require other customized routine husbandry by the animal husbandry staff, beyond what has been described above. Describe the special husbandry needed.

▶

▶ ( ) This ACORP does NOT include use of any animals that will require customized routine husbandry.

N. **Housing Sites**. Document in the tables below each location where animals on this protocol may be housed.

▶ ( ) Housing on VA property. Identify each location on VA property where animals on this protocol will be housed, and indicate whether or not each location is inside the VMU.

Building	Room number	Inside of VMU?	
		Yes	No
		( )	( )
		( )	( )
		( )	( )

▶ ( ) Housing in non-VA facilities. Identify each location not on VA property where animals on this protocol will be housed, and provide the information requested in the table.

Name of Non-VA Facility	Is this facility accredited by AAALAC?	Building	Room Number

	Yes -- enter status*	No**		
	( )	( )**		
	( )	( )**		
	( )	( )**		

*See ACORP Instructions, for a list of AAALAC accreditation status options.

**For any facility listed above that is not accredited by AAALAC, attach documentation that a waiver has been granted by the CRADO.

Special Features

O. **Antibody Production.** Will any of animals on this protocol be used for the production of antibodies?

► ( ) Some or all of the animals on this protocol WILL be used in the production and harvesting of antibodies. Check "Appendix 2" in Item Y, below, and complete and attach Appendix 2, "Antibody Production".

► ( ) NO animals on this protocol will be used in the production and harvesting of antibodies.

P. **Biosafety.** Will any substances (other than those used in routine husbandry or veterinary care) be administered to the animals on this protocol?

► ( ) This protocol INVOLVES administration of substances to the animals other than those used in routine husbandry and veterinary care. Check "Appendix 3" in Item Y, below, and complete and attach Appendix 3, "Biosafety"..

► ( ) This protocol does NOT involve administration of any substances to the animals other than those used in routine husbandry and veterinary care.

Q. **Locations of procedures.** Complete the table below, listing the location(s), inside or outside of the animal facility, for each of the procedures to be performed on animals on this protocol.

Appendix 9: IACUC/OB Protocol Forms

Procedure	Surgical?		Bldg/Room Number	Requires transport through non-research areas?	
	Yes	No		Yes – describe method of discreet transport	No
	( )	( )		( )	( )
	( )	( )		( )	( )
	( )	( )		( )	( )
	( )	( )		( )	( )

R. **Body Fluid, Tissue, and Device Collection.** List each body fluid, tissue, or device to be collected, and complete the table below to indicate the nature of the collection. Check the relevant Appendices in Item Y, below, and complete and attach them, as shown in the column headings.

Body Fluid, Tissue, or Device to be Collected	Collected AFTER Euthanasia	Collected BEFORE Euthanasia		
		Blood Collection Associated with Antibody Production (Appendix 2, "Antibody Production")	Collected as Part of a Surgical Procedure (Appendix 5, "Surgery")	Other Collection from Live Animals (Appendix 4, "Antemortem Specimen Collection")
	( )	( )	( )	( )
	( )	( )	( )	( )
	( )	( )	( )	( )

S. **Surgery.** Does this protocol include any surgical procedure(s)?

► ( ) Surgery WILL BE PERFORMED on some or all animals on this protocol. Check "Appendix 5" in Item Y, below, and complete and attach Appendix 5, "Surgery".

► ( ) NO animals on this protocol will undergo surgery.

T. **Endpoint criteria.** Describe the criteria that will be used to determine when animals will be removed from the protocol or euthanatized to prevent suffering. (Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these criteria. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

▶

U. **Termination or removal from the protocol.** Complete each of the following that applies:

▶ ( ) Some or all animals will NOT be euthanatized on this protocol. Describe the disposition of these animals. (Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these methods of disposition. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

▶

▶ ( ) Some or all animals MAY be euthanatized as part of the planned studies. Complete the table below to describe the exact method(s) of euthanasia to be used. (Use Appendix 9 to document any departures from the standards in the *Guide* represented by these methods. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

Check each method that may be used on this protocol	Method of Euthanasia	Species	AVMA Classification		
			Acceptable	Conditionally Acceptable	Unacceptable
( )	CO_2 from a compressed gas tank Duration of exposure after apparent clinical death▶ Method for verifying death▶ Secondary physical method▶		( )	( )	( )
( )	Anesthetic overdose Agent▶ Dose▶ Route of administration▶		( )	( )	( )
( )	Decapitation under anesthesia Agent▶ Dose▶ Route of administration▶		( )	( )	( )

( )	Exsanguination under anesthesia Agent▶ Dose▶ Route of administration▶		( )	( )	( )
( )	Other (Describe) ▶		( )	( )	( )
( )	Other (Describe) ▶		( )	( )	( )

1. For each of the methods above that is designated as "Conditionally Acceptable" by the AVMA, describe how the conditions for acceptability will be met:
▶

2. For each of the methods above that is designated as "Unacceptable" by the AVMA, give the scientific reason(s) that justify this deviation from the AVMA Guidelines:
▶

3. Identify all research personnel who will perform euthanasia on animals on this protocol and describe their training and experience with the methods of euthanasia they are to use in the species indicated.
▶

4. Instructions for the animal care staff in case an animal is found dead.
   a. Describe the disposition of the carcass, including any special safety instructions. If disposition is to be handled according to a local SOP, enter "according to local SOP" and enter the information requested about the SOP into the table in Item Y.
   ▶

   b. Describe how the PI's staff should be contacted.
   ▶ ( ) Please contact a member of the PI's staff immediately. (Copy the lines below for each individual who may be contacted)

   Name▶

   Contact Information▶

   ▶ ( ) There is no need to contact the PI's staff immediately. Describe the routine notification procedures that will be followed. If the routine notification procedures are described in a local SOP, enter “according to local SOP” and enter the information requested about the SOP into the table in Item Y.

▶

V. **Special Procedures.** List each special procedure (including special husbandry and other special procedures) that is a part of this protocol, and specify where the details of the procedure are documented. See ACORP Instructions, for examples.

Name of Procedure	Identify Where the Details of the Procedure are Documented		
	SOP (title or ID number)*	Other Items in this ACORP -- specify the Item letter(s)	Appendix 6
		Items:	( )**
		Items:	( )**
		Items:	( )**
		Items:	( )**

*If any special procedure is detailed in a SOP, identify the SOP and enter the information requested about the SOP in the table in Item Y.

**If any special procedure is detailed in Appendix 6, check “Appendix 6” in Item Y, below, and complete and attach Appendix 6.

(Use Appendix 9 to document any “departures” from the standards in the *Guide* represented by these procedures. Consult the IACUC or the Attending Veterinarian for help in determining whether any “departures” are involved.)

W. **Consideration of Alternatives and Prevention of Unnecessary Duplication.** These are important to minimizing the harm/benefit to be derived from the work.

1. Document the database searches conducted.
   List each of the potentially painful or distressing procedures included in this protocol.

   ▶

Then complete the table below to document how the database search(es) you conduct to answer Items W.2 through W.5 below address(es) each of the potentially painful or distressing procedures.

Name of the database	Date of search	Period of years covered by the search	Potentially painful or distressing procedures addressed	Key words and/or search strategy used	Indicate which mandate each search addressed			
					Replacement of animals (item W.2)	Reduction in numbers of animals used (item W.3)	Refinement to minimize pain or distress (item W.4)	Lack of unnecessary duplication (item W.5)
					( )	( )	( )	( )
					( )	( )	( )	( )
					( )	( )	( )	( )
					( )	( )	( )	( )

2. Replacement. Describe the replacements that have been incorporated into this work, the replacements that have been considered but cannot be used, and the reason(s) that further replacements are not acceptable.
   ▶

3. Reduction. Describe how the number of animals to be used has been minimized in this protocol and explain why further reduction would disproportionately compromise the value of the data.
   ▶

4. Refinement. Describe the refinements that have been incorporated into this work and explain why no further refinements are feasible.
   ▶

5. Describe how it was determined that the proposed work does not unnecessarily duplicate work already documented in the literature.
   ▶

X. Other Regulatory Considerations.

1. **Controlled drugs.**

Appendix 9: IACUC/OB Protocol Forms

a. Complete the table below for each drug that is used in animals on this protocol and that is classified as a controlled substance by the DEA. See ACORP Instructions, for explanations about the information requested.

Controlled substances	Storage		Personnel Authorized to Access	Location for Use		Procurement	
	Double-locked	Not Double-locked *		VA Property	Not on VA Property	VA Pharmacy	Non-VA
	( )	( )*		( )	( )	( )	( )
	( )	( )*		( )	( )	( )	( )
	( )	( )*		( )	( )	( )	( )

*For any controlled substance that will NOT be stored under double lock, with limited access, describe how it will be stored, and explain why this is necessary.

▶

b. Check each statement below that applies, to confirm that all controlled substances used on this protocol will be procured according to VA pharmacy policies:

▶ ( ) Some controlled substances will used on VA property, and all of these will be obtained through the local VA pharmacy.

▶ ( ) Some controlled substances will not be obtained through the local VA pharmacy, but none of these will be used on VA property. See the ACORP Instructions, for further information.

▶ ( ) Other. Explain▶

2. **Human patient care equipment or procedural areas.** Does this protocol involve use of any human patient care equipment or procedural areas?

▶ ( ) Yes, some human patient care equipment or procedural area(s) will be used for the animal studies on this protocol. Check "Appendix 7" in Item Y, below, and complete and attach Appendix 7, "Use of Patient Procedural Areas for Animal Studies".

Appendix 9: IACUC/OB Protocol Forms

▶ ( ) No human patient care equipment or procedural areas will be used for the animal studies on this protocol.

3. **Explosive agents**. Does this protocol involve use of any explosive agent?

▶ ( ) Yes, some explosive agent(s) will be used on this protocol. Check "Appendix 3" and "Appendix 8" in Item Y, below, and complete and attach Appendix 8, "Use of Explosive Agent(s) within the Animal Facility or in Animals", as well as Appendix 3, "Biosafety".

▶ ( ) No explosive agent(s) will be used as part of this protocol.

Y. **Summary of Attachments.** To assist the reviewers, summarize here which of the following apply to this ACORP.

Appendices. Indicate which of the Appendices are required and have been completed and attached to this protocol. Do not check off or attach any appendices that are not applicable to this ACORP.

▶ (X) Appendix 1, "Additional Local Information" (Required)
▶ ( ) Appendix 2, "Antibody Production"

▶ ( ) Appendix 3, "Biosafety"

▶ ( ) Appendix 4, "Ante-mortem Specimen Collection"

▶ ( ) Appendix 5, "Surgery"

▶ ( ) Appendix 6, "Special Husbandry and Procedures"

▶ ( ) Appendix 7, "Use of Patient Care Equipment or Areas for Animal Studies"

▶ ( ) Appendix 8, "Use of Explosive Agent(s) within the VMU or in Animals"

▶ ( ) Appendix 9, "Departures from "Must" and "Should" Standards in the *Guide*"

Standard Operating Procedures (SOPs). List in the table below, each of the SOPs referred to in this protocol, providing the information requested for each one. The approved SOPs must be included when the approved ACORP and Appendices are submitted for Just-in-Time processing before release of VA funding support.

Item	SOP		Approval Date
	Title	ID	
C.2.c			
M.1			
M.2			
U.4.a			
U.4.b			

V			

Z. **Certifications.** Signatures are required here for any ACORP that is to be submitted to VA Central Office in support of an application for VA funding. Include the typed names and dated signatures as shown below for the Main Body of the ACORP and for each of the Appendices that apply to this protocol. Do NOT include signatures for, or attach, any appendices that do NOT apply.

1. **Main Body of the ACORP.**

a. **Certification by Principal Investigator(s):**

I certify that, to the best of my knowledge, the information provided in this ACORP is complete and accurate, and the work will be performed as described here and approved by the IACUC. I understand that IACUC approval must be renewed at least annually, and that the IACUC must perform a complete *de novo* review of the protocol at least every three years, if work is to continue without interruption. I understand further that I am responsible for providing the information required by the IACUC for these annual and triennial reviews, allowing sufficient time for the IACUC to perform the reviews before the renewal dates, and that I may be required to complete a newer version of the ACORP that requests additional information, at the time of each triennial review.

I understand that further IACUC approval must be secured before any of the following may be implemented:

- Use of additional animal species, numbers of animals, or numbers of procedures performed on individual animals;
- Changing any procedure in any way that has the potential to increase the pain/distress category to which the animals should be assigned, or that might otherwise be considered a significant change from the approved protocol;
- Performing any additional procedures not already described in this ACORP;
- Use of any of these animals on other protocols, or by other investigators.

I further certify that:

- No personnel will perform any animal procedures on this protocol until the IACUC has confirmed that they are adequately trained and qualified, enrolled in an acceptable Occupational Health and Safety Program, and meet all other criteria required by the IACUC. When new or additional personnel are to work with the animals on this protocol, I will provide this information to the IACUC for confirmation before they begin work;
- I will provide my after-hours contact information to the animal care staff for use in case of emergency.

Appendix 9: IACUC/OB Protocol Forms

Name(s) of Principal Investigator(s)	Signature	Date

b. **Certification by IACUC Officials.**

We certify that:

- We, with the IACUC, have evaluated the care and use of animals described on this ACORP, in accordance with the provisions of the USDA Animal Welfare Act Regulations and Standards, PHS Policy, the *Guide for the Care and Use of Laboratory Animals*, and VA Policy;
- The IACUC has determined that the care and use of animals described in this ACORP is appropriate, and has therefore approved the protocol;
- The full text of any minority opinions is documented here as indicated below:

► ( ) No minority opinions were submitted by any IACUC participant for inclusion.

► ( ) Minority opinions submitted by IACUC participants are copied here

►

► ( ) Minority opinions submitted by IACUC participants are attached on separate pages labeled "IACUC Minority Opinion" (indicate the number of pages►)

Name of Attending Veterinarian (VMO or VMC)	Signature	Date
(b)(6)		
Name of IACUC Chair	Signature	Date
(b)(6)		

2. **Appendix 2. Antibody Production.** No signatures required.

Appendix 9: IACUC/OB Protocol Forms

3. Appendix 3. Biosafety.

a. Certification by PI(s) and IACUC Officials:

We certify that:

- Before any animal experiments involving hazardous agents (identified in Item 10.a of Appendix 3) are performed, SOPs designed to protect all research and animal facility staff as well as non-study animals will be developed and approved by the appropriate VA or affiliated university safety committee and by the IACUC;
- All personnel who might be exposed to the hazardous agents (identified in Item 10.a of Appendix 3) will be informed of possible risks and will be properly trained ahead of time to follow the SOPs to minimize the risks of exposure.

Name(s) of Principal Investigator(s)	Signature(s)	Date
Name of Institutional Veterinarian	Signature	Date
Name of IACUC Chair	Signature	Date

b. Certification by Biosafety Official. I certify that:

- Each agent to be administered to animals on this protocol has been properly identified in Item 1 of Appendix 3 as to whether it is "toxic", "infectious", "biological", or "contains recombinant nucleic acid";
- The use of each of the agents thus identified as "toxic", "infectious", or "biological", or "contains recombinant nucleic acid" is further documented as required in Items 4, 5, 6, and/or 8, as applicable, and in Item 10.a of Appendix 3;
- The use of each of these agents has been approved by the appropriate committee(s) or official(s), as shown in Item 10.a of Appendix 3.

Name of the Biosafety Officer, or of the Chair of the Research Safety or Biosafety Committee	Signature	Date

c. **Certification by Radiation Safety Official.** I certify that:

- Each agent to be administered to animals on this protocol has been properly identified in Item 1 of Appendix 3 as to whether it is "radioactive";
- The use of each radioactive agent is further documented as required in Items 7 and 10.a of Appendix 3;
- The use of each radioactive agent has been approved by the appropriate committee(s), as shown in Item 10.a of Appendix 3.

Name of the Radiation Safety Officer, or of the Chair of the Radiation Safety or Isotope Committee	Signature	Date

4. **Appendix 4. Ante-mortem Specimen Collection.** No signatures required.

5. **Appendix 5. Surgery. Certification by the PI(s).** I certify that:

- To the best of my knowledge, the information provided in Appendix 5 of this ACORP is complete and accurate;
- The surgical procedures will be performed and the post-operative care (including administration of post-operative analgesics) will be provided as described;
- The spaces where any survival surgical procedures will be performed (listed in Item 4 of Appendix 5) are suitable for sterile/aseptic surgery;
- The names and contact information for research personnel to notify or consult in case of emergencies will be provided to the VMU supervisor and veterinary staff;
- Post-operative medical records will be maintained and readily available for the veterinary staff and the IACUC to refer to, and will include the following:
    - Identification of each animal such that care for individual animals can be documented.

- Daily postoperative medical records for each animal, that include documentation of daily evaluation of overall health and descriptions of any complications noted, treatments provided, and removal of devices such as sutures, staples, or wound clips;
- Documentation of the administration of all medications and treatments given to the animals, including those given to reduce pain or stress.
- Daily records covering at least the period defined as "post-operative" by local policy.
- The signature or initials of the person making each entry.

Name(s) of Principal Investigator(s)	Signature(s)	Date

6. **Appendix 6. Special Husbandry and Procedures.** No signatures required.

7. **Appendix 7. Use of Patient Care Equipment or Areas for Animal Studies.**

    a. **Certification by the Principal Investigator(s).** I certify that, to the best of my knowledge, the information provided in Appendix 7 of this ACORP is complete and accurate, and the use of patient care equipment or areas for these animal studies will be as described.

Name(s) of Principal Investigator(s)	Signature(s)	Date

    b. **Certification by the officials responsible for the use of any human patient care equipment in animal procedural areas.** Each of the following must sign to indicate that they have granted approval for the human patient care equipment to be moved to the VMU or other animal procedural area to be used on animals and then returned to the human patient care area, as described in Appendix 7. Leave this section blank, if not applicable.

Name of IACUC Chair	Signature	Date
(b)(6)		

Name of the Manager of the Human Patient Care Equipment	Signature	Date

c. **Certification by the officials responsible for the use of the equipment in human patient care areas for these animal studies.** Each of the following must sign to indicate that they have granted approval for animals to be transported into human patient care areas for study or treatment, as described in Appendix 7. Leave this section blank, if not applicable.

Name of IACUC Chair	Signature	Date
Name of Attending Veterinarian (VMO or VMC)	Signature	Date
Name of the Chair of the Clinical Executive Board, or the Service Chief responsible for the Patient Care Area and Equipment	Signature	Date
Name of ACOS for R&D	Signature	Date
Name of Chief of Staff	Signature	Date
Name of Director or CEO of the Facility (Hospital or Clinic)	Signature	Date

8. **Appendix 8. Use of Explosive Agent(s) within the Animal Facility or in Animals.**

Appendix 9: IACUC/OB Protocol Forms

a. **Certification by the Principal Investigator(s).**

I certify that, to the best of my knowledge, the information provided in Appendix 8 of this Animal Component of Research Protocol (ACORP) is complete and accurate, and the use of explosive agents in these animal studies will be as described.

I further certify that:

- Procedures involving explosive agent(s) will be performed within a properly operating, ventilated safety hood;
- All electrical equipment operating when explosive agent(s) are in use will be positioned and powered outside of the hood;
- Once the seal is broken on any containers of explosive agents, they will be kept in a safety hood throughout use, stored in an explosion-proof refrigerator or other approved storage area, and discarded properly once completely emptied;
- Proper procedures will be used for safe and appropriate disposal of items (including animal carcasses) that may contain residual traces of the explosive agent(s).

Name(s) of Principal Investigator(s)	Signature(s)	Date

b. **Certification by the officials responsible for overseeing the use of explosive agent(s) in this protocol.** Each of the following must sign to verify that they or the committee they represent have granted approval.

Name of IACUC Chair	Signature	Date
Name of Attending Veterinarian (VMO or VMC)	Signature	Date
Name of Safety/Biosafety Officer for the Facility	Signature	Date

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Name of ACOS for R&D	Signature	Date
Name of VISN Regional Safety Officer	Signature	Date

9. **Departures from "Must" and "Should" Standards in the *Guide*.** No signatures required.

Appendix 9: IACUC/OB Protocol Forms

ACORP Appendix 1

ADDITIONAL LOCAL INFORMATION

VERSION 4

(This appendix may be used to collect additional information required by the local IACUC. See ACORP App. 1 Instructions, for more detailed explanations of the information requested.)

Due to the specifics of the Animal Component of Research Protocol (ACORP) the following personnel training is required for each personnel listed on the protocol:

This section is to be completed during the pre-review of the ACORP by the Veterinary Medical Officer (VMO):

A. According to the ACORP, the following training is required of personnel on this protocol:

1. Use of patient care facilities: _____ YES _____ NO
2. Breeding: _____ YES _____ NO
3. Surgical: _____ YES _____ NO
4. Antibody production: _____ YES _____ NO
5. IACUC training _____ YES _____ NO
6. LMS General Training _____ YES _____ NO

______________________________ ______________

(b)(6) Date

This section is to be completed by the Principal Investigator after the pre-review by the VMO to the full review by the IACUC:

B. All personnel cited in the protocol are required to submit the documentation of the completion of training to the Research Service prior to the start of work on the protocol.

_____ Please list all personnel on this protocol:

_____ Please attach all documentation to the back of this form for submission to the IACUC

______________________________ ______________

Signature of Principal Investigator Date

Appendix 9: IACUC/OB Protocol Forms

ACORP APPENDIX 2

ANTIBODY PRODUCTION

VERSION 4

See ACORP App. 2 Instructions, for more detailed explanations of the information requested.

1. **Immunization.** Provide the information requested below for any animals to be used for raising antibodies specifically for use in this protocol.

   a. Describe the immunization protocol in the table below, using a separate row for each day on which any agent (including primer, antigen, and/or adjuvant) will be administered. (Make sure that each primer, antigen, and adjuvant is also included in Appendix 3.)

Immunization day (e.g. day -7, 0, 7, 30, etc.)	Antigen		Adjuvant – give name, concentration, and volume (ml)	Total injection volume (ml) per animal (antigen plus adjuvant)	Divided among how many injection sites?	Injection route and location of injection site(s) on body
	Name	Total amount (mg) and volume (ml)				

   b. Describe how each antigen will be screened to make sure that it does not harbor infectious agents that could infect other laboratory animals or people after injection.
   ▶

   c. List possible adverse effects that might be observed in animals receiving the proposed primer, antigen, and/or adjuvant injections, and describe the measures that will be taken if these adverse effects occur:
   ▶

   d. Give the justification for using any primer or adjuvant that is expected to cause pain or distress in the animals.
   ▶

2. **Survival Blood Collection.** Will blood be collected as a survival procedure for the production and harvesting of antibodies on this protocol?

► ( ) No, the production and harvest of antibodies on this protocol does not involve survival collection of blood.

► ( ) Yes, this protocol requires the collection of blood in a survival procedure, before (as a "pre-bleed") and/or after immunization. Make sure this is included in Item R of the ACORP, and complete items 2.a, 2.b, and 2.c, below.

a. Describe each survival collection of blood in the table below, including any "pre-bleeds" prior to immunizations:

Site of Blood Collection	Amount of Blood Collected at any one time, expressed as volume (ml) and as % of body weight (assume 1 ml = 1 gram)	Number of Blood Collections	Time Interval(s) Between Successive Collections	Volume Replace-ment? (yes/no)

b. Will anesthetics, tranquilizers, or analgesics be administered for blood collection?

► ( ) No anesthetics, tranquilizers, or analgesics will be administered for blood collection. Explain why it is appropriate or necessary NOT to administer pain-relieving agents:

►

► ( ) Yes. Describe the administration of pain-relieving agents, including the name of each agent, and its dose (mg/kg), volume (ml), and route and frequency/duration of administration (Make sure this information is also included in Appendix 3):

►

c. Will volume replacement be provided for blood that is collected?

► ( ) Volume will NOT be replaced for some of the blood collection listed. For each collection listed in Item 2.a, above, for which volume will NOT be replaced, explain why not.

►

► ( ) Volume WILL be replaced for some of the blood collection listed. For each collection listed in Item 2.a, above, for which volume WILL be replaced, describe the replacement(s) that will be provided (including the composition of the replacement(s), volume, and route of administration).

►

3. **Terminal Blood Collection.** Will animals be euthanatized by exsanguination, for harvest of antibodies?

► ( ) No, this protocol does NOT involve terminal blood collection for harvest of antibodies.

► ( ) Yes, this protocol DOES require terminal blood collection for the harvest of antibodies. Make sure this is included in Item R of the ACORP, and complete Items 3.a., 3. b., and 3.c., below:

a. Describe the method(s) to be used for euthanasia and exsanguination:
►

b. Will anesthetics, tranquilizers, or analgesics be administered for exsanguination?

► ( ) No anesthetics, tranquilizers, or analgesics will be administered for the exsanguination(s). Explain why it is appropriate or necessary NOT to administer pain-relieving agents:

►

► ( ) Yes. Describe the administration of pain-relieving agents including the name of each agent, and its dose (mg/kg), volume (ml), and route and frequency/duration of administration (Make sure this information is also included in Appendix 3):

►

c. Describe how you will make sure that the animals are dead after collection of the blood:
▶

4. **Harvesting Feeder Cells.** Describe the exact procedures (including administration of pain-relieving agents) that will be used on any donor animals from which feeder cells will be collected for this protocol, and estimate the number of animals needed for this purpose. Make sure that these animals are included in Item I of the ACORP, and that the harvesting of feeder cells is included in Item R of the ACORP.
▶

5. **Expansion of Hybridoma Cell Line(s) *in vivo*.** Will any animals be used to expand hybridoma cell lines so that antibody can be harvested from ascites fluid?

▶ ( ) No animals will be used on this protocol for *in vivo* expansion of hybridoma cell lines.

▶ ( ) Yes, this protocol requires use of some animals for *in vivo* expansion of hybridoma cell lines. Make sure that the animals used for this are included in Item I of the ACORP, the priming agent and the hybridoma cells are documented in Appendix 3, and the collection of ascites fluid is included in Item R of the ACORP. Complete items 5.a, 5.b, and 5.c, below.

a. Explain why alternate research methods that do not require the use of additional animals (e.g., *in vitro* cell culture systems for harvesting monoclonal antibodies) are not adequate to meet the research objectives of this project.
▶

b. Complete the following table to summarize the procedures to be performed in expanding the hybridoma cell lines and collecting ascites fluid:

Hybridoma cell line designation	Number of animals to be used for ascites production	Priming agent and volume	Number and timing of priming injections	Volume of injected hybridoma cells	Number of abdominal taps before euthanasia

c. Describe the exact procedures (including administration of pain-relieving agents) that will be used for the abdominal taps to be performed on this protocol
▶

d. List the criteria for euthanasia of animals prior to the last planned abdominal tap.
▶

Appendix 9: IACUC/OB Protocol Forms

(Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these procedures. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

Appendix 9: IACUC/OB Protocol Forms

ACORP APPENDIX 3
BIOSAFETY
VERSION 4

See ACORP App. 3 Instructions, for more detailed explanations of the information requested.

1. **Summary of All Materials Administered to Animals on this Protocol.** Complete the table below for all materials to be administered to any animal on this protocol, indicating the nature of the material by marking EVERY box that applies, and indicating the BSL number for any infectious agents:

Material (Identify the specific agent, device, strain, construct, isotope, etc.)	**Source** (Identify the vendor or colleague, or specify which animals on this protocol will serve as donors)	**Nature of Material**						
		Toxic Agent (Item 4)	Infectious Agent (Item 5) -- Enter the CDC Biosafety Level (BSL 1, 2, 3, or 4)	Biological Agent (Item 6)	Radioactive Agent (Item 7)	Contains Recombinant Nucleic Acid (Item 8)	Routine Pre- or Post-Procedural ☐Drug	Euthanasia agent
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )

Appendix 9: IACUC/OB Protocol Forms

2. **Summary of How Materials will be Administered.** Complete the table below for each of the materials shown in the table in Item 1 above:

Material* (Identify the specific agent, device, strain, construct, isotope, etc.)	**Dose** (e.g., mg/kg, CFU, PFU, number of cells, mCi) and **Volume** (ml)	**Diluent* or Vehicle***	**Route** of admin	**Frequency or duration** of admin	**Reason** for Administration and **Expected Effects**	Location of **Further Details** in this ACORP (specify "Main Body" or "App #", and identify the Item)	Administration Under **Anesthesia, sedation, or tranquilization** (Y/N)

*Each material, diluent, or vehicle that is listed as FDA approved or is labeled "USP" is pharmaceutical grade. Check on-line for formulations that are FDA approved for administration to humans (http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm) or animals (http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/UCM042847). Designate with a * each material and each diluent or vehicle to be used that is not pharmaceutical grade. For each of these, explain here why the use of a non-pharmaceutical grade formulation is necessary, and describe how it will be ensured that the material is suitable for use. (See ACORP App. 3 Instructions, for specifics about the level of detail required.)

▶

3. **Anesthesia, Sedation, or Tranquilization.** Complete 3.a. and 3.b. below:

   a. For each material with "Y" entered in the last column of the table in Item 2 above, describe the anesthesia, sedation, or tranquilization to be used, identifying the anesthetic, sedative, or chemical tranquilizer, and detailing the dose, volume, and route of administration (Make sure that these agents are also included in Item 1 of this appendix, as materials to be administered):
   ▶

b. For each material with "N" entered in the last column of the table in Item 2 above, explain why no anesthesia, sedation, or tranquilization is necessary, or can be provided, and describe any alternate methods of restraint that will be used.
▶

4. **Toxic Agents.** Complete the table below for each of the materials listed as a "toxic agent" in the table in Item 1 above, checking the all of the properties that apply (see ACORP App. 3 Instructions, for details).

Name of Toxic Agent	a. Mutagen	b. Carcinogen	c. Teratogen	d. Select Agent?			e. Other – specify toxic properties
				Not a Select Agent	Select Agent Used in Sub-threshold Quantities	Select Agent that Requires Registration/Approval	
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶

*For each "select agent" that requires registration/approval (copy the lines below for each agent):

Name of agent ▶

Registered with CDC or USDA ▶

Registration Number ▶

Registration Date ▶

Expiration Date of Registration ▶

Name of official who granted approval on behalf of VACO▶

Date of approval▶

5. **Infectious Agents.** Complete the table below for each of the materials listed as an "infectious agent" in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

Name and BSL Number of Infectious Agent	a. ABSL Number *	b. Drug Sensitivity Panel Available? (Describe)	c. Select Agent?		
			Not a Select Agent	Select Agent used in Sub-threshold quantities	Select Agent that Requires Registration/Approval
		(Yes/No)	( )	( )	( )**
		(Yes/No)	( )	( )	( )**
		(Yes/No)	( )	( )	( )**
		(Yes/No)	( )	( )	( )**
		(Yes/No)	( )	( )	( )**
		(Yes/No)	( )	( )	( )**

*Complete the following for each agent for which the ABSL Number given is less than the BSL Number shown (copy the lines below for each agent):

Name of agent ▶

Justification for applying ABSL measures that are less protective than those recommended ▶

**For each "select agent" that requires registration/approval (copy the lines below for each agent):

Name of agent ▶

Registered with CDC or USDA ▶

Registration Number ▶

Registration Date ▶

Expiration Date of Registration ▶

Name of official who granted approval on behalf of VACO▶

Date of approval▶

6. **Biological Agents.** Complete the table below for each of the materials listed as a "biological agent" in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

Name of Biological Agent	Screening for Infectious Agents

7. **Radioactive Agents.** Complete the table below for each of the agents listed as a "radioactive agent" in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

Name of Radioactive Agent (specify the isotope)	Authorized Individual	Approving Committee or Official

8. **Agents Containing Recombinant Nucleic Acid.** For each of the materials checked in the table in Item 1, above, as "contains recombinant nucleic acid", indicate which of the conditions applies (see ACORP App. 3 Instructions, for details).

Name of Agent that Contains Recombinant Nucleic Acid	Subject to the *NIH Guidelines for Research Involving Recombinant DNA Molecules*	Exempt
	( )	( )
	( )	( )
	( )	( )

	( )	( )
	( )	( )
	( )	( )

9. **Potential for Pain or Distress.** Complete the table below for each of the agents listed in Item 1, above, that is expected to have potentially painful or distressing effects on the animals (see ACORP App. 3 Instructions, for details).

Name of Agent	Nature of Potential Pain/Distress	Measures to Alleviate Pain/Distress

10. **Protection of Animal Facility Staff from Hazardous Materials.** Complete Items 10.a and 10.b, below, for each of the agents listed in the table in Item 1, above, as "toxic", "infectious", "biological", "radioactive", or "contains recombinant nucleic acid" (detailed in Items 4 – 8). This item specifically addresses members of the animal facility staff; protection of the research staff from each of these agents must be addressed in Item G of the main body of the ACORP. See ACORP App.3 Instructions, for details.

a. Complete the table below.

Name of Hazardous Agent	Approving Committee or Official	Institution (VA or affiliate)	Names of Animal Facility Staff Members at Risk

b. Detail how the individuals listed in the table above (Item 10.a.) have been (or will be) informed of the possible risks of exposure, and have been (or will be) trained to avoid exposure to these agents.
▶

11. **Signatures.** Provide the applicable signatures on the signature pages (Item Z.3) of the main body of this ACORP.

Appendix 9: IACUC/OB Protocol Forms

ACORP Appendix 4
ANTEMORTEM SPECIMEN COLLECTION

VERSION 4

See ACORP App. 4 Instructions, for more detailed explanations of the information requested.

1. **Summary.** Complete the table below for each specimen to be collected from a live animal on this protocol (see ACORP App. 4 Instructions, for details).

Specimen Collected	Site and Method of Collection	Anesthesia (Yes/No)	Amount Collected Each Time	Volume Replacement (Yes/No/NA)	Total Number of Collections per Animal	Time Intervals Between Successive Collections

2. **Use of Anesthetics, Tranquilizers, or Analgesics.**

   a. For each specimen described in Item 1, above, as being collected WITHOUT anesthesia, complete Items 2.a(1) and 2.a(2), below:

      (1) Explain why no measures will be taken to prevent pain (e.g., because of scientific requirements described here, or because the collection method involves no more than minor or momentary pain).
      ▶

      (2) Completely describe any method of physical restraint that may be used.
      ▶

   b. For each specimen described in Item 1, above, as being collected WITH anesthesia, complete the following table:

Anesthetic, tranquilizer, or analgesic agent	Dose (mg/kg) and volume (ml)	Route of administration	Frequency of administration

3. **Volume Replacement for Fluid Collections.**

   a. For each fluid specimen described in Item 1, above, for which NO volume replacement will be provided, explain why not.
   ▶

   b. For each fluid specimen described in Item 1, above, for which volume replacement WILL be provided, describe the replacement fluids that will be administered (including their composition, volume, and route of administration).
   ▶

4. **Monitoring the animals.** Detail how the animals will be monitored after collection of specimens to ensure that they recover appropriately (see ACORP App. 4 Instructions, for details).
▶

Appendix 9: IACUC/OB Protocol Forms

ACORP Appendix 5
SURGERY

VERSION 4

See ACORP App. 5 Instructions, for more detailed explanations of the information requested.

1. **Surgery Classification.** Complete the table below for each surgery included in this protocol, and indicate how it is classified (terminal, minor survival, major survival, one of multiple survival). See ACORP App. 5 Instructions, for details.

Surgery		Terminal	Survival		
#	Description (specify the species, if ACORP covers more than one)		Minor	Major	One of Multiple *
1		( )	( )	( )	( )*
2		( )	( )	( )	( )*
3		( )	( )	( )	( )*
4		( )	( )	( )	( )*

*If survival surgery (including major surgeries and any minor surgeries that may induce substantial post-procedural pain or impairment) will be performed as part of this protocol in addition to any other such surgery (on this or another protocol) on the same individual animal, complete items 1.a and 1.b, below:

a. Provide a complete scientific justification for performing the multiple survival surgeries on an individual animal:
►

b. Give the interval(s) between successive surgeries, and the rationale for choosing the interval(s):
►

2. **Description of Surgeries.** Describe each surgery listed in Item 1, providing enough detail to make it clear what the effects on the animal will be. (Pre-operative preparation, anesthesia, and post-operative recovery will be covered in items 5, 6, and 7, below.)

Surgery 1 ►

Surgery 2 ►

Surgery 3 ►

Surgery 4 ►

3. **Personnel.** Complete the table below for each individual who will be involved in any of the surgeries on this protocol.

Name	Surgery #(s) (see Item 1)	Role in Surgery			
		Surgeon	Assistant	Manage Anesthesia	Other (describe)
		( )	( )	( )	( )
		( )	( )	( )	( )
		( )	( )	( )	( )
		( )	( )	( )	( )
		( )	( )	( )	( )

4. **Location of surgery.** Complete the table below for each location where surgery on this protocol will be performed.

Building	Room Number	Surgery #(s) (see Item 1)	Type of Space		
			Dedicated Surgical Facility	Other Dedicated Surgical Space	Other Space not Dedicated to Surgery
			( )	( )*	( )*
			( )	(*)	( )*
			( )	( )*	( )*
			( )	( )*	( )*

*For each space that is not in a dedicated surgical facility, provide the justification for using this space for surgery on this protocol

▶

5. **Pre-operative protocol.**

   a. **Pre-operative procedures.** Complete the table below for each pre-operative procedure that will be performed to prepare the animal(s) for surgery.

Surgery #(s) (see Item 1)	Fast (Specify Duration)	Withhold Water (Specify Duration)	Place Intravenous Catheter(s) (Specify Site(s))	Other – Describe
1	( )--	( )--	( )--	( )--
2	( )--	( )--	( )--	( )--
3	( )--	( )--	( )--	( )--
4	( )--	( )--	( )--	( )--

   b. **Pre-operative medications.** Complete the table below. Include agent(s) for induction of anesthesia, as well as any other pre-treatments that will be administered prior to preparation of the surgical site on the animal.

Agent	Surgery #(s) (see Item 1)	Dose (mg/kg) & volume (ml)	Route of administration	Frequency of administration (e.g., times/day)	Pre-operative period of treatment (e.g., immediate, or # of days)

   c. **Pre-operative preparation of the surgical site.** For each surgery, identify each surgical site on the animals, and describe how it will be prepared prior to surgery.

Surgery 1 ▶

Surgery 2 ►

Surgery 3 ►

Surgery 4 ►

6. **Intra-operative management.**

   a. **Intra-operative medications.** Complete the table below for each agent that will be administered to the animal during surgery.

Agent	Paralytic*	Surgery #(s) (see Item 1)	Dose (mg/kg) & volume (ml)	Route of administration	Frequency of dosing
	( )*				
	( )*				
	( )*				

   * For each agent shown above as a paralytic, explain why its use is necessary, and describe how the animals will be monitored to ensure that the depth of anesthesia is sufficient to prevent pain.

   ►

   b. **Intra-operative physical support.** For each surgery, describe any physical support that will be provided for the animals during surgery (e.g., warming, cushioning, etc.).
   ►

   c. **Intra-operative monitoring.** Describe the methods that will be used to monitor and respond to changes in the state of anesthesia and the general well-being of the animal during surgery.
   ►

7. **Survival surgery considerations.** For each survival surgical procedure indicated in Item 1 and described in Item 2, complete Items 7.a. – 7.g.

Appendix 9: IACUC/OB Protocol Forms

a. Complete the table below for each survival surgery listed in Item 1, above.

Surgery # (see Item 1)	Survival Period	Measures for Maintaining Sterility							
		Sterile Instruments	Surgical Cap	Sterile Gloves	Surgical Scrub	Sterile Drapes	Sterile	Face Mask	Other*
		( )	( )	( )	( )	( )	( )	( )	( )*
		( )	( )	( )	( )	( )	( )	( )	( )*
		( )	( )	( )	( )	( )	( )	( )	( )*
		( )	( )	( )	( )	( )	( )	( )	( )*

* Describe any "other" measures to be taken to maintain sterility during surgery.

▶

b. For each surgery, describe the immediate post-operative support to be provided to the animals.

Surgery 1 ▶

Surgery 2 ▶

Surgery 3 ▶

Surgery 4 ▶

c. Post-operative analgesia. Complete the table below for each surgery listed in item 1, above.

Surgery # (see Item 1)	Agent*	Dose (mg/kg) & Volume (ml)	Route of Administration	Frequency of Dosing (e.g., times/day)	Period of treatment (e.g. days)
1					

2					
3					
4					

*For each surgery for which NO post-operative analgesic will be provided, enter "none" in the "Agent" column, and explain here why this is justified:

►

d. Other post-operative medications. Complete the following table to describe all other medications that will be administered as part of post-operative care.

Surgery # (see Item 1)	Medication	Dose (mg/kg) & Volume (ml)	Route of Administration	Frequency of dosing (e.g. times/day)	Period of treatment (e.g. days)

e. Post-operative monitoring. After-hours contact information for the personnel listed must be provided to the veterinary staff for use in case of an emergency.

(1) Immediate post-operative monitoring

Surgery # (see Item 1)	Frequency of Monitoring	Duration at this Frequency	Name(s) of Responsible Individual(s)

(2) Post-operative monitoring after the immediate post-operative period

Surgery # (see Item 1)	Frequency of Monitoring	Duration at this Frequency	Name(s) of Responsible Individual(s)

f. Post-operative consequences and complications.

(1) For each surgery, describe any common or expected post-operative consequences or complications that may arise and what will be done to address them.

Surgery 1 ▶

Surgery 2 ▶

Surgery 3 ▶

Surgery 4 ▶

(2) List the criteria for euthanasia related specifically to post-operative complications:

Surgery 1 ▶

Surgery 2 ▶

Surgery 3 ▶

Surgery 4 ▶

(3) In case an emergency medical situation arises and none of the research personnel on the ACORP can be reached, identify any drugs or classes of drugs that should be avoided because of the scientific requirements of the project. (If the condition of the animal requires one of these drugs, the animal will be euthanatized instead.)
▶

g. Maintenance of post-surgical medical records. Complete the table below for each surgery, specifying where the records will held, and identifying at least one individual who will be assigned to maintain accurate, daily, written post-surgical medical records. Indicate whether the named individuals are research personnel involved in this project, or members of the veterinary staff.

Surgery # (see Item 1)	Location of Records	Name(s) of Individual(s) Responsible for Maintaining Written Records	Research Personnel	Veterinary Staff
1			( )	( )
2			( )	( )
3			( )	( )
4			( )	( )

8. **Certification.** The PI must sign the certification statement in Item Z.5 of the main body of the ACORP.

Appendix 9: IACUC/OB Protocol Forms

ACORP APPENDIX 6
SPECIAL HUSBANDRY AND PROCEDURES

VERSION 4

See ACORP App. 6 Instructions, for more detailed explanations of the information requested.

1. **Description of Procedures.** Complete the table below for each procedure listed in Item V of the main body of the ACORP that is not detailed in a SOP or in another item or Appendix of the ACORP. For each special procedure, check all features that apply.

Special Procedure		Features							
Number	Brief Description	Husbandry	Restraint	Noxious Stimuli	Exercise	Behavioral Conditionin	Irradiation	Imaging	Other**
1		( )	( )	( )	( )	( )	( )	( )	( )
2		( )	( )	( )	( )	( )	( )	( )	( )
3		( )	( )	( )	( )	( )	( )	( )	( )
4		( )	( )	( )	( )	( )	( )	( )	( )

*Husbandry refers to all aspects of care related to the maintenance of the animals, including (but not limited to) provision of an appropriate diet, access to water, control of environmental conditions, and the selection of primary and secondary enclosures.

**Describe any "Other" features that are involved.

▶

a. Provide a complete description of each special procedure listed above, including the duration of the procedure, how frequently it will be repeated in any one animal, and any effects it is expected to have on the animal:

Special Procedure 1 ▶

Special Procedure 2 ▶

Special Procedure 3 ►

Special Procedure 4 ►

b. Explain why each of these special procedures is necessary:

Special Procedure 1 ►

Special Procedure 2 ►

Special Procedure 3 ►

Special Procedure 4 ►

2. **Personnel.** Complete the table below for each special procedure listed in Item 1, above. Identify the individual(s) who will be responsible for carrying out the procedures, and those who will be responsible for monitoring the condition of the animals during and after the procedures. After-hours contact information for the personnel listed must be provided to the veterinary staff for use in case of an emergency.

Procedure Number (see Item 1)	Responsible Individual(s)	
	Carrying Out Procedure	Monitoring the Animals
1		
2		
3		
4		

3. **Potential Pain or Distress.** Complete the table below for each special procedure identified in Item 1, above, indicating for each procedure, whether potential pain and/or distress is expected, and, if

so, describing the potential pain and/or distress and indicating whether any measures are to be taken to prevent or alleviate it.

Procedure Number (see Item 1)	Expected Potential Pain and/or Distress			
	No	Yes		
		Description	To Be Relieved	Not to Be Relieved
1	( )		( )[a]	( )[b]
2	( )		( )[a]	( )[b]
3	( )		( )[a]	( )[b]
4	( )		( )[a]	( )[b]

a. For each procedure for which potential pain and/or distress is expected, but WILL be prevented or alleviated by administration of the analgesic(s) or stress-relieving agents, complete the table below:

Procedure Number (see Item 1)	Agent	Dose (mg/kg) & vol (ml)	Route of admin	Freq of admin (times/day)	Duration of admin (days post-procedure)
1					
2					
3					
4					

Describe any non-pharmacological measures to be taken to address the potential pain and/or distress:

Special Procedure 1 ►

Special Procedure 2 ►

Special Procedure 3 ►

Special Procedure 4 ►

b. For each procedure for which potential pain and/or distress is expected and will NOT be prevented or alleviated, provide the scientific justification for this:

Special Procedure 1 ►

Special Procedure 2 ►

Special Procedure 3 ►

Special Procedure 4 ►

4. **Monitoring.** Describe how the condition of the animals will be monitored during and after each of the special procedures, and list the criteria that will be used to determine when individual animals will be removed from groups undergoing these procedures, because of pain or distress (see ACORP App. 6 Instructions, for details):

Procedure Number (see Item 1)	Monitoring Methods	Endpoint Criteria
1		
2		
3		
4		

ACORP APPENDIX 7

USE OF PATIENT CARE EQUIPMENT AND/OR AREAS FOR ANIMAL STUDIES

Version 4

See ACORP App. 7 Instructions, for more detailed explanations of the information requested.

1. **Full Name(s) of Principal Investigator(s) ▶**

2. **Equipment to be Used.**

   a. Identify the equipment ▶

   b. Procedure(s) to be performed with this equipment ▶

   c. Describe how contamination of the human patient care equipment will be prevented and how the equipment will be cleaned/sanitized before its subsequent use for human patients.
   ▶

3. **Human Patient Care Procedural Areas to be Used.**

   a. Location(s) ▶

   b. Animal species to be studied or treated ▶

   c. Number of individual animals to be studied or treated ▶

   d. Date(s) ▶

   e. Time(s) of day ▶

   f. Procedure(s) to be performed on the animals in these areas ▶

   g. Protection and cleaning of patient care room surfaces ▶

   h. Benefits to VA patients. Briefly describe how this use of the human patient care areas for research on animal subjects potentially benefits VA patients.
   ▶

i. Necessity for use of human patient care areas. Explain why this work on animal subjects cannot be performed within the animal facility or a research laboratory area.
▶

j. Animal transport. Describe how the animals will be transported back and forth between the animal housing area and the human patient care areas.
▶

k. Preventing human patients and patient care personnel from being affected by the presence of the animals. Provide detailed descriptions of the measures to be taken to address noises and odors, allergens, and zoonotic pathogens associated with the animals.
▶

4. **Signatures.** Provide the signatures required on the signature pages (Item Z.7) of the main body of this ACORP.

Appendix 9: IACUC/OB Protocol Forms

ACORP APPENDIX 8

USE OF EXPLOSIVE AGENT(S) WITHIN THE VMU OR IN ANIMALS

VERSION 4

See ACORP App. 8 Instructions, for more detailed explanations of the information requested.

1. **Full name(s) of Principal Investigator(s)** ▶

2. **Explosive agents to be used.**

   a. Identify the explosive agents. Complete the table below.

Agent Number	Name(s) Used to Refer to the Agent in This ACORP	Name Shown for this Agent on the MSDS on File	CAS number	Location of the MSDS on File
1				
2				
3				
4				

   b. Locations where the explosive agents will be used. Complete the table below.

Agent Number	Location Where Agent Will Be Used			
	Building	Room Number	Within the VMU	Outside of VMU
1			( )	( )
2			( )	( )
3			( )	( )
4			( )	( )

   c. Procedure(s) to be performed. Briefly describe the use of each of the explosive agents on this protocol and explain why it is necessary to use these agents (why non-explosive replacements cannot be used instead).
   ▶

d. Precautions to be taken to prevent explosions. Describe the measures to be taken to store, use, and dispose of safely each explosive agent and any materials contaminated with it, and to prevent the generation of sparks in its presence. See ACORP App. 8 Instructions, for a list of commonly used precautions.
▶

e. Period of use.
Beginning no earlier than (date) ▶

Ending no later than (date) ▶

f. Animals that will be administered explosive agents:
Species ▶

Approximate weights of individual animals ▶

Approximate number of animals ▶

3. **Personnel.** Complete the table below for each individual who will handle any of the explosive agents as part of this protocol.

Name of Individual	Explosive Agent(s) to be Handled	Training and Experience Pertinent to Handling Explosive Agents

4. **Signatures.** Provide the signatures required on the signature pages (Item Z.8) of the main body of this ACORP.

Appendix 9: IACUC/OB Protocol Forms

ACORP Appendix 9

DEPARTURES FROM "MUST" AND "SHOULD" STANDARDS IN THE *GUIDE (2011)*

VERSION 4

See ACORP App. 9 Instructions, for more detailed explanations of the information requested.

For each IACUC-approved "departure" of this protocol from a "Must" or "Should" standard in the *Guide*, provide the following information. (Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.):

Copy the lines below for each departure.

Briefly summarize the "Must" or "Should" standard, and provide the number(s) of the page(s) on which it appears in the *Guide*

▶

Describe the specific alternate standard(s) that will be met on this protocol, and how they will be monitored.

▶

Provide the scientific, veterinary medical, or animal welfare considerations that justify this departure

▶

Appendix 9: IACUC/OB Protocol Forms

Form 2.

Animal Use Protocol Modification Form
Cincinnati VA Medical Center

Use this form to submit amendments to your currently approved animal use protocol. It will be reviewed in an expedited fashion. **Type all entries.** Complete items #1-5 on the form and answer items # 6-10 in a narrative form. Submit the amendment to the VA Research Service, 3200 Vine Street (b)(6), Cincinnati, Ohio 45220. Phone Number – 475-6328

1. Principal Investigator: Name: Phone: E-mail:
   Signature: ______________________________ Date:
2. Protocol Number:
3. Protocol Title:
4. Type of Amendment: Proposed change in (check all that apply):

- ☐ animal species
- ☐ animal numbers
- ☐ animal use procedures
- ☐ animal care procedures
- ☐ other (please specify in writing)

- ☐ personnel
- ☐ use of potentially hazardous substances: radioisotopes, hazardous chemicals, infectious agents, recombinant DNA (including use or generation of transgenics)

Complete each of the following items in narrative form below or on separate pages.
Write "N/A" if not applicable.

5. Describe and justify any proposed changes in the animal species or numbers listed in your approved protocol. For each species, clearly indicate the amount of any proposed increase in the total number of animals to be used per year.

6. Describe and justify any proposed changes in the animal use and/or care procedures described in your approved protocol.

7. Describe and justify any proposed changes in the use of potentially hazardous substances.

8. For new personnel, describe their qualifications, when they took or plan to take IACUC training and how they will be trained in performing animal procedures. New individuals must complete Occupational Health and Safety forms and be current with training *prior* to receiving full protocol approval. .

9. Describe any other proposed changes to your approved protocol.

Appendix 9: IACUC/OB Protocol Forms

FORM 3.

ANIMAL COMPONENT OF RESEARCH PROTOCOL (ACORP) Review

Name of Principal Investigator:
Proposal #:

Proposal Overview
Description and Experimental Design.

Personnel
Training, Occupational Safety and Health concerns.

Animal Information
(Use of principles of 3 "R's": Replacement, or utilizing non-animal models; Reduction of numbers of animals used; and Refinement, or elimination or reduction of unnecessary pain and distress)

Animal Housing and Care
Husbandry, Housing, Specialized care or behavior, Housing site

Experimental Procedures
Antibody production, Test substance administration, Procedures, Transportation, Body Fluid, Tissue, and Device Collection, Surgery. Endpoint Criteria. Euthanasia. Special Procedures (not covered by standard SOP's)

Other Regulatory Considerations.
Controlled drugs, Human patient procedural areas, Explosive anesthetic agent use

Appendices

Appendix 1, "Use of Non-VA Animal Facility"
Appendix 2, "Antibody Production"
Appendix 3, "Test Substances"
Appendix 4, "Antemortem Specimen Collection"
Appendix 5, "Surgery"
Appendix 6, "Special Husbandry and Procedures"
Appendix 7, "Request to Use Patient Care Procedural Areas for Animal Studies
Appendix 8, "Request to Use Explosive Agent
Appendix 9, "Training Requirements"

Other Comments

Date:

Reviewer:

Appendix 9: IACUC/OB Protocol Forms

Form 4.

DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER
Institutional Animal Care and Use Committee
ANNUAL PROTOCOL PROGRESS REPORT

Investigator Name:_______________ ACORP #: __________________

Protocol Title: ____

Period of report: ____________________ Species used: __________

Year of study/reporting period (circle one): 1 2 3

Proposed number of animals from approved protocol:

Category B:	Category C:
Category D:	Category E:

Total number of animals purchased, weaned, transferred in; or euthanized prior to weaning during reporting period:

Date animal numbers were received from Managing Director of the VMU: ________________

Number of animals categorized (euthanized prior to weaning or sacrificed) during report:

Category B:	Category C:
Category D:	Category E:

Projected Duration of ACORP (month/year): _______________

1. Have any experimental procedures, utilized in this protocol, been changed since its inception?
   No_______ Yes_____

2. Have any changes been made in this protocol since its inception as necessitated by update of AAALAC Regulation?
   No_______ Yes______

If you answered yes to question 1 or 2, then describe on a separate page all changes made in order, listing the pages in the old protocol where these changes apply, if it has not already been approved by IACUC.

3. Are there any SOP's related to this ACORP regarding special procedures?
   No_______ Yes _____

If Yes, please include an updated, signed and dated copy of the SOP with the progress report.

4. Number of animals purchased with VA funds and housed off-site:_______

I CERTIFY THE INFORMATION STATED ABOVE IS CORRECT:

____
INVESTIGATOR'S SIGNATURE DATE

IT IS MANDATORY THIS FORM BE COMPLETED AND SIGNED IN ITS ENTIRETY AND RETURNED TO (b)(6) @va.gov in RESEARCH SERVICE (151) no later than _____________

For IACUC use only:
Date of Approval:_________ IACUC Chair Signature___________________________

revised 2/2018

Appendix 10: IACUC/OB Periodic Report

VA SEMIANNUAL EVALUATION
of the
INSTITUTIONAL ANIMAL CARE AND USE PROGRAM AND FACILITIES
Part 1 – Checklist
Section A. Review of the Program

The Review of the Program is largely an administrative evaluation of all of the policies, plans, standard procedures, and systems under which the institution fulfills its responsibilities to ensure humane animal care and use. Some of the programmatic items may appear similar to items included in Section B (Inspection of the Facilities), but the focus here (Review of the Program) is on what is intended or expected, while Section B focuses on observed implementation.

NOTE: The checklist is designed to prompt review according to regulatory requirements, and focuses on the minimum standards that must be met. The wording in the checklist is not to be interpreted as altering the regulatory requirements in any way, but represents guidance from the office of the CVMO. For specifics about the regulatory requirements and recommended best practices, the references provided in square brackets must be consulted:

"1200.01" refers to the "VHA Handbook 1200.01, Research and Development (R&D) Committee",
"1200.07" refers to the "VHA Handbook 1200.07, Use of Animals in Research",
"PHS" refers to the "PHS Policy on Humane Care and Use of Laboratory Animals",
"9 CFR" refers to the "USDA Animal Welfare Act Regulations and Standards, Code of Federal Regulations, Title 9",
"US Govt Principle" refers to the "US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training", and
"Guide" refers to the National Research Council's "Guide for the Care and Use of Laboratory Animals", 8th edition, 2011

Instructions:

1) Enter identifying information in the header above:
   Double click in the header area.
   Then enter text after each ":"
      (Note: Federal regulations require that a new Review of the Program be completed every 6 months *[PHS (IV.B.1); 9 CFR (2.31(c)(1))]*, and a new Inspection of the Facilities *[PHS (IV.B.2); 9 CFR (2.31(c)(2))]* be completed every 6 months. The "Date of Semiannual Evaluation" is the date on which the last of the components of the semiannual evaluation was completed.)
   Double click in the document area to return to the main body of the form.

2) Enter the information requested below. The "▶" symbols indicate **required** information:

▶Date(s) of the most recent previous Review of the Program: 1/16/2018
▶Date(s) on which this Review of the Program was conducted: 7/17/2018

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Names of voting IACUC members who participated in the Program Review:
(The Program Review team must include a minimum of two voting members of the IACUC [9 CFR (2.31(c)(3))]. Any non-members who also participate, at the discretion of the IACUC, may be listed in the second table.)

Name	Specific Role on IACUC (if any)	Date(s) of Participation
(b)(6)		Absent
		Absent
		7/17/18
		7/17/18
		7/17/18
		Absent
		7/17/18
		Absent
		Absent
		Absent
		7/17/18

Non-IACUC members who participated in the Program Review:

Name	Title	Date(s) of Participation
(b)(6)		7/17/18
		7/17/18

3) For each item in the checklist, type "X" in the column that applies (shaded cells should not be used):

Not Applicable
Acceptable
Approved Departure (Approved by the IACUC)
Minor Deficiency
Significant Deficiency

4) For each item marked as an Approved Departure, a Minor Deficiency, or a Significant Deficiency here (Part 1, Section A), provide details in Part 2 of this form.

5) Items that reflect changes in the 8th edition of the *Guide* are flagged as follows, and may require particular attention as the 8th edition is implemented.

‡ denotes a new "must" item
† denotes a new "should" item

Appendix 10: IACUC/OB Periodic Report

I. Institutional Policies and Responsibilities

A. Shared Responsibilities

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
100†	A formal written MOU, contract, or agreement is in place for any arrangement in which the VA shares responsibility for animal research with any other institution. This includes the use of an external IACUC and any collaborative arrangements for support, housing, or use of animals in research. *[1200.07 (8.b(1)); Guide, p. 15]* ▶ Name(s) of other institution(s) and the date(s) on which current formal written understanding(s) took effect: **UC 9/29/16 and CCHMC 6/28/2016**		X			

B. General IACUC Function

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
150	The official appointment of each member of the IACUC by the CEO *[PHS (IV.A.3a); 9 CFR (2.31(a))]* is documented and specifies the duration of the appointment and any specific role to which the member is appointed. *[1200.07 (8.a)]*		X			
151	The IACUC has at least five members, including at least one member qualified for and appointed to each of the required roles. *[PHS (IV.A.3); Guide (p. 24)]*		X			
152‡	The IACUC meets as necessary to fulfill responsibilities. *[Guide (p.25)]*		X			
153	The IACUC has adequate authority, administrative support, and other resources to fulfill its responsibilities. *[Guide (p. 14-15)]*		X			
154†	The IO has authority to allocate needed resources. *[Guide (p.13)]*		X			

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155	The IACUC communicates regularly with the R&D Committee, by providing the R&D Committee with a set of final, signed, IACUC minutes, and all other notifications required by the R&D Committee, and through an individual who regularly attends meetings of both the IACUC and the R&D Committee. *[1200.07 (8.h (2)); 1200.01 (11.j)].*		X			
156†	Program needs are regularly communicated to the IO by the AV and/or the IACUC. *[Guide (p. 13)]*		X			
157	The IACUC communicates effectively as needed with the SRS and/or the IBC. *[1200.07 (Appendix C-.8.a)]*		X			
158	All minority opinions that are submitted are included in the final document that results from any action of the IACUC (e.g., meeting minutes, report of semiannual evaluation, and reports to oversight entities). *[PHS (IV.B.); 9 CFR (2.31(c)(3)]*		X			
159	The research office provides packets to IACUC members no later than 3 business days before the IACUC meeting. This packet must include an agenda with all business items listed, including reviewer assignments for all new protocols. *[1200.07(8.f(2)(d))]*		X			
160	A written draft of the minutes of the latest IACUC meeting is provided to all IACUC members at least 1 week before the next meeting.		X			
161	Review and approval by the IACUC is required before any work related to the use of animal subjects in VA research begins or is changed significantly. *[1200.07(8f(2));PHS (IV.B.6-7); 9CFR (2.31(c)(6-7)); Guide (p. 26)]*		X			
162	All protocol forms used comply with PHS Policy and USDA AWAR. *[PHS(IV.C);9 CFR (2.31(d)]*		X			
163	The current version of the VA ACORP (or an alternate form that has been approved by the CVMO) is used for any protocol involving work to be supported with VA funding. *[1200.07 (8.f(2)(e))]*		X			
164‡	Consultation with a qualified laboratory animal veterinarian is required before a protocol may be submitted for review by the IACUC. Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol.*[1200.07 (Appendix D - 1.k(2)); 9 CFR (2.31(d)(1)(iv)(B);. Guide (p.5)]*		X			
165‡	No IACUC member participates in the review or approval of any protocol in which that member has a real or apparent conflict of interest (financial or otherwise). *[Guide (p. 26)]*		X			

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166	The IACUC does not approve any protocol that involves use of hazardous agents until the Biosafety Official and/or the Radiation Safety Official, as applicable, has signed in Item Z to confirm that the hazardous agents are properly documented in the ACORP, *[1200.07 (Appendix C-.8.c(1)); Guide (p. 21)]*		X			
167	Use of any patient care area for VA-funded animal research is prohibited unless the IACUC and appropriate local clinical and administrative officials first grant approval and the IACUC has reviewed and approved a completed ACORP Appendix 7 that justifies no reasonable alternative to the use of human clinical areas or equipment exists. *[1200.07 (7.k(1))]*	X				
168†	A system of post-approval monitoring is in place to ensure that all work with research animals is performed according to IACUC approved protocols. *[Guide (p. 33)]*		X			
169	The IACUC conducts continuing reviews of all protocols annually. *[9 CFR (2.31(d)(5)]*		X			
170	IACUC approval of each protocol expires on or before the third anniversary of its initial approval. *De novo* review and approval of a complete updated protocol by the IACUC before the date of expiration is required for work on the protocol to continue beyond three years without interruption. *[PHS (IV.C.5)]*		X			
171	Humane endpoints are established for studies in which pain and/or distress is anticipated (i.e., tumors, infectious disease, vaccine challenges, trauma, etc.) *[Guide (p.27)]*		X			
172	The IACUC has established oversight procedures for pilot and field/wildlife studies; studies involving genetically modified animals, food/fluid restriction, and the use of pharmaceutical versus non-pharmaceutical grade chemicals receive special consideration by the IACUC. *[Guide (p. 27-33)]*		X			
173	Surgical procedures are determined to be major or minor, multiple surgical procedures on a single animal are justified and the outcome evaluated, and multiple survival procedures regardless of species conform to regulated species standards. *[Guide (p.30)]*		X			
174‡	Requests for exemptions from major survival procedure restrictions are made to the USDA/APHIS through the IO. *[Guide (p. 30)]*		X			
175	Toe-clipping is approved by the IACUC only when no other individual identification method is feasible; the procedure is performed aseptically and with pain relief. *[Guide (p.75)]*		X			

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176‡	The use of restraint devices is justified in the animal use protocols. IACUC approval is given when the purpose and duration of the restraint are justified. The justification addresses: the lack of feasible alternatives to physical restraint, provisions for the removal of maladaptive animals, training of animals, and appropriate observation of restrained animals. Veterinary care is provided if lesions or illness associated with restraint occur. *[Guide (p 29-30]*		X			
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**
200	Program Review -- At least every six months, the IACUC reviews the animal care and use program. For VA animals used at an affiliate institution, this is done according to the MOU in place between the VA facility and the affiliate. *[1200.07 (8.f(1)); PHS (IV.B.1); 9CFR (2.31(c)(1))]*		X			
201	Facilities Inspection -- At least every six months, the IACUC inspects all facilities in which animals in the VA animal research program are used. For VA animals used at an affiliate institution, this is done according to the MOU in place between the VA facility and the affiliate. *[1200.07 (8.f(1)); PHS (IV.B); 9CFR (2.31(c)(2))]*		X			
202	Under no circumstances is the report of any semiannual evaluation altered after it has been signed by the IACUC. *[1200.07 (8.f (1)(f))]*		X			
203	The report of each semiannual evaluation of the animal care and use program, signed by the IACUC, is discussed personally with the Director of the VA facility in a meeting with at least one representative voting member of the IACUC. *[1200.07 (8.f(1)(e)); PHS (IV.B); 9 CFR (2.31(c)(5); Guide (p. 25)]*		X			
204	Within 60 days of approval by the IACUC, the report of each semiannual evaluation, signed by the facility Director, is submitted to the CVMO (ORD), or the CVMO's office is notified of the reason for delay and the expected date of submission. *[1200.07(8.k(3))]*		X			
D. Standard Operating Procedures (SOPs)						

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
250	At least annually, the IACUC oversees a review of the complete set of all local SOPs by the Attending Veterinarian with the VMU supervisor and other qualified personnel. *[1200.07 (7.c)]* ▶ Date of latest review: **March 20, 2018**		X			
	E. Addressing Concerns about Animal Welfare					
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**
300‡	The responsibility for animal well-being is assumed by all members of the program; therefore, procedures are in place for the IACUC to receive, review, investigate, and address internal or external concerns or allegations about animal care and use. *[PHS (IV.B); 9 CFR (2.31(c)(4)); Guide (p. 1;23-24)]*		X			
301	Procedures are in place to protect "Whistle-blowers" from discrimination or reprisal for reporting potential regulatory violations within the animal care and use program. *[9CFR (2.32(c)(4)); Guide (p. 24)]*		X			
302	Any animal activity may be suspended by the IACUC (by a majority vote of a quorum), or immediately and unilaterally by the facility Director or any other official designated by the facility Director. *[1200.07 (8.)j; 9 CFR (2.31(c)(8) and 2.31(d)(6))]*		X			
303	The IACUC notifies local administrators (facility Director, RCO, ACOS/R&D) and external oversight entities (CVMO, ORO, OLAW, and AAALAC) immediately when an investigation is undertaken. *[1200.07 (8.i)]*		X			
304	Within 5 business days of determining that a reportable deficiency has occurred, the IACUC submits an initial report to the facility Director and the IO, with copies to the ACOS/R&D and other relevant research review subcommittees. *[1058.01(8.e); PHS (IV.F.3); 9 CFR (2.31(c)(3) and 2.31(d)(7))]*		X			

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305	Within 5 business days (*ORO requirement*) of receiving a report of a reportable deficiency from the IACUC, the facility Director and IO submit the report to the CVMO, ORO, OLAW, AAALAC, the Animal Care Section of USDA APHIS, and any other non-VA funding sources, as applicable, with copies to the IACUCs of any affiliate institutions with shared responsibility. *[1058.01(8.e); PHS (IV.F.3); 9 CFR (2.31(c)(3) and 2.31(d)(7))]*		X			
306	The corrective action plan, the timetable for its implementation, and interim and final reports on the correction of each reported deficiency are submitted to the facility Director and IO, and through them to the CVMO, ORO, OLAW, AAALAC, the Animal Care Section of USDA APHIS, and any other non-VA funding sources, as applicable, with copies to the IACUCs of any affiliate institutions with shared responsibility. *[1200.07 (8.i)]*		X			
F. Reporting to Oversight Entities						
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**
350	The USDA Annual Report of Research Facility was completed and submitted by December 1 within the past year, as required by USDA, and a copy is on file locally. *[9CFR (2.36)]* ▶ Date of most recent submission: **11/28/17**		X			
351	The VA facility is covered by a PHS Assurance, approved by OLAW, and revised as needed to reflect any significant changes in the animal care and use program. *[PHS (IV.A)]* ▶ Name of the Institution that holds the PHS Assurance: Cincinnati VA Medical Center ▶ Effective date of most recent approved Assurance: **02/3/2017**		X			
352	The annual report to OLAW was submitted within the past year by the end of the month immediately following the end of the last reporting period, and a copy is on file locally. *[PHS (IV.F.1-2)]* ▶ Date of most recent submission: **1/18/2018**		X			
353	The VA facility is fully accredited by AAALAC, and a copy of the triennial comprehensive AAALAC Program Description is on file locally. *[1200.07 (7.e)]* ▶ Name of the Institution that holds the accreditation: Cincinnati VA Medical Center (539)		X			

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354	The AAALAC Annual Report was submitted within the past year as required by AAALAC, and a copy is on file locally. *[1200.07 (8.l(2)(b))]* ▶Date of most recent submission: **1/3/2018**		X			
355	The VA Veterinary Medical Unit (VMU) annual report, which includes mice and rats, was submitted online by the specified deadline (usually January 15) within the past year. *[1200.07 (8.l(4))]*		X			
356	All other correspondence with oversight entities (USDA, OLAW, AAALAC, and ORO) relevant to the animal research program (except for routine notifications and reminders) is copied to the CVMO within 15 days of receipt or submission. *[1200.07 (9)]*		X			
357	All documents relevant to the animal care and use program are maintained on file for at least three years, or according to the latest VA requirements (current VA policy requires all records to be kept indefinitely), whichever is longer. This includes acquisition/disposition records, IACUC meeting minutes, semiannual reports, and all reports to, and correspondence with, oversight entities. *[1200.07 (Appendix E-2. c); 9CFR2.35(f); PHS (IV.E)]*		X			
358	All documents relevant to individual studies are maintained for at least the duration of the study and for three additional years after the completion of the study, or according to the latest VA requirements (current VA policy requires all records to be kept indefinitely), whichever is longer. *[1200.07 (8.f(1)(h));9CFR2.35(f); PHS (IV.E)]*		X			

G. Personnel Qualifications and Training

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
400‡	The IACUC does not approve any protocol until each individual listed on the protocol has documented completion of required VA training at the prescribed intervals. *[1200.07 (8.m(1)).; PHS (IV.A.1.g); 9 CFR (2.32); Guide (p. 15); US Government Principle VIII)]*		X			
401‡	The IACUC confirms that each individual is appropriately trained before approving that individual to perform the procedure without supervision. This includes non-surgical and surgical procedures, anesthesia monitoring, and euthanasia. *[PHS (IV.C.1.f); 9 CFR (2.31(d)(1)(viii); Guide (p. 15 & 115)]*		X			

402‡	All personnel are documented as being appropriately trained for their positions, and participating in formal and/or on-the-job continuing education at the prescribed intervals. *[1200.07 (8.m); PHS (IV.A.1.g); 9 CFR (2.32); Guide (p. 16-17)]*		X			
403†	IACUC members receive training in all aspects of humane animal care and use through the documented completion of VA training at the required intervals. *[PHS (IV.A.1.g); 9 CFR (2.32); 1200.07 (8.m); Guide (p.17)]*		X			
H. Occupational Health and Safety						
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**
Occupational Health and Safety Program (OHSP)						
450‡	An OHSP has been established and is maintained by the VA facility to protect personnel involved in animal research (laboratory or field setting) from associated risks including but not limited to direct animal contact, exposure to unfixed tissues or fluids, hazardous agents used in the research, etc. *[PHS (IV.A.1.f); Guide (p.17; 32); 1200.07 (10)]*		X			
451	All personnel at risk of exposure have the opportunity to participate in the OHSP. This includes personnel whose duties include work with animals (e.g., VMU staff, investigators, research technicians), regardless of whether they are paid employees, without compensation (WOC) personnel, students, or trainees, as well as , personnel that do not have contact but are exposed to animals (e.g., maintenance and engineering staff assigned to the VMU, other service personnel, etc.). *[1200.07 (10.a); Guide (p. 18)]*		X			
452	**Hazard Identification and Risk Assessment** – The IACUC, the local veterinarians, the SRS, and the Safety Officer work together effectively to identify potential hazards that exist in the animal research program, to assess the consequent risks to personnel, and to determine appropriate strategies to manage the risks. *[Guide (p. 18-19)]*		X			
453	**OHSP Training** – Training is provided to all personnel covered by the OHSP, with regard to personal hygiene practices, use of safety equipment, and SOPs appropriate to each individual's duties and risks of exposure. *[Guide (p. 20)]*		X			
The OHSP – Facilities and Procedures						

454	**Ergonomic efficiency** – Procedures and policies are in place to reduce the risks of ergonomic injuries to personnel (e.g. facility design, SOPs, and the use of equipment such as ramps, carts, and hydraulic lifts). *[Guide (p.19- 20)]*		X			
455	**Control of exposure** – Personal exposure to hazardous agents is limited through the design of the facility, establishment of SOPs (e.g. separation of animals treated with hazardous agents from untreated animals), selection/maintenance/certification of safety equipment (e.g., showers, eyewash stations, fume hoods, etc.), and careful monitoring of agents to ensure that they remain within permissible ranges. *[Guide (p. 19-20)]*		X			
456	**Policies and Procedures associated with nonhuman primates (NHPs)** – have been established and include training with regard to the risks of exposure to *Macacine herpesvirus 1* (formerly *C. herpesvirus* or Herpes B virus); tuberculosis screening for exposed personnel; training on and the handling of bites, scratches, or other injuries; medical evaluation and treatment of injuries; and provision of appropriate PPE. *[Guide (p. 23)]*	X				
The OSHP – Personal Hygiene						
457	The OHSP includes guidelines on appropriate personal hygiene practices, including hand washing and showering, use of protective clothing, and restricting consumption of food and beverages to designated break areas. *[Guide (p. 20-21)]*		X			
458	The VA facility provides uniforms, laundry service, and all other necessary personal protective equipment (e.g., gloves, ear protection, protective eyewear, steel-toed footwear, respirators, with appropriate fit testing and training, and other special equipment), as appropriate to the duties of the personnel. *[Guide (p. 20-22)]*		X			
The OHSP – Medical Evaluation and Preventive Medicine for Personnel						
459	A pre-employment medical evaluation is performed on each prospective new employee. *[1200.07(Appendix C-4(2)(a))]*		X			
460	A follow-up medical evaluation is performed at routine intervals (usually annually) on each OHSP participant. *[1200.07(Appendix C-.4(2)(b))]*		X			
461	Enrollment in OHSP is prerequisite to approval for access to the VMU and for beginning work with animals. *[1200.07(Appendix C-4(2)(c))]*		X			

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462	Personnel are not permitted to decline immunizations or tests required by the VA facility that are necessary to protect the health of the animals or personnel. *[1200.07 (10.b)]*		X			
463	All vaccines (e.g., tetanus, rabies) are provided to personnel as currently recommended by CDC, free of charge. *[1200.07 (10,f(2)); Guide (p. 23)]*		X			
464	Personnel are required to report and be treated for all injuries and illnesses potentially related to working in the VMU or other animal research areas, or otherwise in connection with work with animals. *[1200.07(Appendix C-4.b; Guide (p. 23)]*		X			
465‡	The program considers confidentiality and other legal factors as required by federal, state and local regulations. *[Guide (p. 22)]*		X			
466‡	If serum samples are collected, the purpose is consistent with federal and state laws. *[Guide (p. 22)]*	X				

II. Physical Plant

• **General**						
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**
500	The physical plant infrastructure (includes HVAC, plumbing, lighting, power, control systems, etc.) is adequate to support the needs and performance standards of the animal care and use program, and is compliant with and meets all applicable building codes.*[Guide (p. 133-136)] – Ask the committee to see if they're in agreement*		X			
501	Policies and procedures are in place to ensure that facilities and equipment are properly maintained and functional. *[Guide (p. 133-136)]*		X			

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III. Operations Related to Animal Environment, Housing, and Management

• Physical Environment						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
Temperature, Humidity, and Ventilation						
550	The response of facilities management (FM) personnel to elevations in temperature in animal rooms is tested and reported to the IACUC at least annually, and the response by FM personnel is satisfactory. *[1200.07 (7.a(2)(c))].* ▶ **Date of latest test:1/9/2018**		X			
551	HVAC reheat units serving animal rooms are designed so as to fail in the "off" position, preventing over-heating of animals. *[1200.07 (7.a(2)(a))]*		X			
Noise						
522	Policies are in place to minimize exposure of the animals and personnel to excessive vibration, unnecessary sounds, and any sounds louder than 85dB. *[Guide (p.49-50)]*			X		

B. Husbandry						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
General						
600‡	Oversight of daily husbandry and other animal care duties has been assigned to a single individual (usually, the VMU Supervisor) when a full-time veterinarian is not available on site. *[Guide (p. 14)]*		X			
Population Management						
601	Methods of animal identification have been established, which provide the protocol number and other pertinent information. Where applicable, genotype information is provided using accurate, consistent, and unambiguous genotype nomenclature. *[Guide (p. 75-77)]*		X			
Behavioral Management						
602	**Activity** – Each animal must have opportunities to engage in activity (motor, cognitive, and social) appropriate to its species. *[Guide (p. 60;63)]*		X			

603	**Social Environment** – Animals must be housed in appropriate compatible social groups or when single housing of social species is required (by an approved protocol or because of veterinary concerns) have contact with compatible conspecifics and/or enrichment. *[Guide (p.51, 63-65)]*			X		
604	**Environmental Enrichment** – The program to enrich the structural environment of each animal (structural additions, exercise, manipulative activities, and cognitive challenges) to accommodate the expression of species-typical postures and behavior is reviewed regularly by the IACUC, researchers, and veterinarians. *[Guide (p. 52-54)]*			X		

C. Animal Procurement and Transportation

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
650‡	Only animals that are obtained lawfully may be used in VA research. *[1200.07(7.b(1)); Guide (p.106)]*		X			
651	Animal procurement is approved and initiated only after confirmation that: (1) the source of animals is appropriate; (2) appropriate housing and care for the animals upon arrival is coordinated with animal care staff; and (3) the animals are designated for use on an IACUC approved protocol. *[Guide (p. 106-109)]*		X			
652‡	Transportation (including intra-institutional, inter-institutional, interstate, international, and from commercial or non-commercial sources) complies with federal and international regulations, as applicable, and is arranged to protect the health and safety of the animals and humans (passersby as well as personnel involved in the work with the animals), to minimize stress on the animals, and to ensure animal biosecurity. *[Guide (p. 107); 9 CFR (Part 3, Standards)]*		X			

D. Preventive Medicine

	Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency

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700	The institutional animal care and use program strives to maintain research animal populations that are as free of infectious agents as possible. *[1200.07 (7.d(1))]*		X			
701	A program of veterinary care, overseen by a VMO or VMC, is in place for the surveillance, diagnosis, treatment, and control of non-protocol diseases or conditions (especially those with zoonotic potential, such as Q-fever, LCMV, parasites, etc.), and for the management of diseases or conditions induced by experimental requirements. *[Guide (p. 112-114)]*		X			
702	Quarantine and stabilization of newly received animals, as well as, separation of animals by species, source, health status, and intended use, as appropriate, are used to prevent spread of pathogens. *[Guide (p. 109-112)]*		X			
E. Waste Disposal						
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**
750	Procedures are in place for sanitation of waste containers, as well as procedures for safe removal and disposal of conventional, biological, and hazardous wastes (including soiled bedding). All waste disposal procedures comply with facility, municipal and federal policies and regulations. *[Guide (p. 73-74)]*		X			
F. Pest Control						
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**
800	A regularly scheduled and documented program of monitoring for and controlling pests has been implemented, which includes measures to prevent vermin entry and harborage. *[Guide (p. 74)]*		X			
801	Animal and human health concerns encourage the use of non-toxic methods of pest control instead of chemical pesticides whenever possible. If chemical pesticides are to be used, the investigators whose animals may be exposed are consulted to ensure that scientific objectives are not unnecessarily compromised. *[Guide (p.74)]*		X			
G. Medical Supplies						

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
850	All controlled substances needed for animal research on VA property are ordered and received by the local VA pharmacy, and dispensed to research personnel as needed. *[1200. 07 (7.m)]*		X			
851	Use of non-pharmaceutical grade compounds, expired drugs or medical supplies (e.g., sutures, antiseptics, etc.) in animals is limited to protocols in which such use has been documented not to jeopardize animal welfare or compromise the validity of the study. *[PHS (FAQ F.4); Guide (p.31)]*		X			

H. Emergency, After Hours, Weekend, and Holiday Animal Care

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
900	Qualified personnel are assigned to provide routine care for the animals on weekends and holidays. *[Guide ((p. 74);* 9 CFR (2.33(b))]		X			
901	Veterinary care is available as needed after regular work hours on weekends, and on holidays; procedures are in place for timely notification of a veterinarian in case emergency care is needed. *[Guide (p, 74);* 9 CFR (2.33(b))]		X			
902‡	A disaster plan that addresses the needs of both personnel and animals is in place including animal euthanasia if necessary; the plan is approved by the IACUC. *[Guide (p. 35;75)]*		X			
903†	The disaster plan addresses triage procedures, emergency/life support services; preservation of irreplaceable animals, essential personnel, and disaster response training. The animal facility plan is approved by institution, is a component of the overall disaster plan, and is provided to first responders. *[Guide (p. 35; 75)]*		X			
904	Key animal facility personnel (e.g., the Attending Veterinarian and the VMU supervisor) are included among the official responders to be contacted in emergencies that involve animals. *[Guide (p.75)]*		X			

IV. Veterinary Medical Care

A. Role of the Veterinarians

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		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
950 ‡	A high quality veterinary care program consistent with ethical standards has been established. *[Guide (p. 105)]*		X			
951 ‡	Each VMO and VMC has training and/or experience in lab animal medicine and with the species used. *[Guide (p. 15); 9 CFR (2.33)]*		X			
952†	The VMOs and VMCs provide guidance to research personnel with regard to the humane care and use of the animals in the context of the scientific and regulatory requirements (including appropriate handling of animals, sedation, anesthesia, surgery and peri-operative care, analgesia, and euthanasia). *[Guide pg. 105-106, 113-114; 9 CFR (2.31(d)(1)(iv)(B) and 2.33(b)(4-5))]*		X			
953	When veterinary care services are provided by a part-time or consulting veterinarian, the veterinarian's visits are of sufficient frequency to meet programmatic needs. A written program of veterinary care for USDA regulated species is in place if a full-time attending veterinarian is not on-site. *[Guide (p. 14);USDA-APHIS Policy #3]*		X			
954 ‡	Veterinary care is available as needed and effective procedures are established for timely reporting of animal injury, illness, or disease and for veterinary assessment, treatment, or euthanasia. The veterinarian is authorized to treat, relieve pain, and/or euthanize. *[Guide ((p. 106, 113, 114, 120, and 122-123);* 9 CFR (2.33(b))*]*		X			
955 ‡	The Attending Veterinarian has the authority and resources needed, and uses them appropriately to manage all aspects of animal care and use in the animal research program. *[Guide (p. 14); 9 CFR 2.33(a)(2)]*		X			
956 ‡	Veterinary access to all animals is provided. *[Guide (p. 14)]*		X			

B. Surgery

	Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency

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1000	Aseptic technique is required for all survival surgery; is appropriate to the species; and includes preparation of the patient, surgeon, sterile materials, and supplies, as well as appropriate operative technique to reduce the risk of infection. *[9CFR (2.31(d)(1)(ix); Guide (p.118-119)]*		X			
1001	Procedures are in place to ensure that appropriate surgical anesthesia and analgesia are provided. Postoperative monitoring and care are provided by trained personnel and documented. *[Guide (p. 119-120)*		X			
1002	Major surgical procedures in non-rodents may be performed only in dedicated surgical facilities. *[9CFR (2.31(d)(1)(ix))]*		X			
1003	A system of ongoing and thorough assessment of surgical outcomes is in place to ensure that appropriate procedures are followed and appropriate corrective changes are implemented in a timely manner. *[Guide (p. 115)]*		X			
1004	Presurgical planning includes veterinary input and addresses location, supplies, anesthetic and analgesic use, peri-operative care, recordkeeping, etc. *[Guide (p.116)]*		X			
1005	For nonsurvival surgery, the surgical site is clipped, gloves are worn, and the surgical area and instruments are clean. *[Guide (p.118)]*		X			

C. Pain, Analgesia, and Anesthesia

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
1050	Guidelines for the assessment and management of pain, distress, and animal wellbeing have been established, and include monitoring for effectiveness of pain control, consideration of non-pharmacologic pain control methods, and guidance regarding the selection and use of anesthetics and analgesics. *[Guide (p. 121-122)]*		X			
1051 ‡	Procedures are in place to assure anti-nociception before surgery begins. *[Guide, p 122)]*		X			
1052	Special precautions for the use of paralytics are in place to ensure adequate anesthesia. *[Guide (p 123)]*	X				

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		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
1053 ‡	The drug storage and control program complies with federal regulations for human and veterinary drugs; procedures have been established to ensure that analgesics and anesthetics are used prior to their expiration date. *[Guide (p.115)]*		X			
1054 †	Anesthetics and analgesics are acquired, stored, and disposed of in a legal and safe manner; drug records and storage procedures are reviewed during facility inspections. *[Guide, p. 115 & 122)]*		X			
	D. Euthanasia					
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**
1100	The methods of euthanasia approved by the IACUC are consistent with the AVMA recommendations for the species involved. *[Guide (p. 123); PHS (IV.C.1.g); 9 CFR (2.31(d)(1)(xi))]*		X			
1101	Personnel receive training on euthanasia methods appropriate for the species and age of the animal to minimize the potential for pain and distress. *[Guide (p. 123-124)]*		X			
1102 ‡	Procedures and training are in place to ensure that death is confirmed. *[Guide (p. 124])*		X			

V. Animal Care and Use Program Work Orders

Instructions: Enter work order data as prompted for Tables 1 and 2. All work orders related to the animal care and use program should be entered, whether or not they resulted from a semiannual evaluation. Use Table 3 to summarize the work orders in Tables 1 and 2.

Table 1: Work Orders Completed - include all work orders completed since the previous semiannual program evaluation (▶Date(s) of previous evaluation: January 16, 2018

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#	Enter M, S, or No, for Minor or Significant deficiency noted in semiannual evaluation, or Not related to	Work order (local reference) number	Summarize work requested	Date work order was submitted	Date work order was completed	Elapsed days from submission to completion
1	No	33314453	Need door threshold sealed with silicone.	1/24/18	1-25-18	1
2	No	33314563	Need hallway floor scraped and painted	1/24/18	2-23-18	30
3	No	40398856	water supply hoses dripping under sink	2/23/18	2-26-18	3
4	No	40400577	Please remove old coat hooks, patch and paint, hang new ones	2/23/18	3-5-18	10
5	No	51883958	Faucet leaking	4/10/18	4-20-18	10
6	No	51725188	2 light bulbs out, need replaced, In hallway not 107	4/9/18	4-11-18	2
7						
8						
9						
10						
11						

Table 2: Work Orders Not Yet Completed - include all open work orders generated by previous semi-annual evaluations and other sources. Work orders placed as a result of the current semi-annual review are also entered below:

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#	Enter M, S, or No, for Minor or Significant deficiency noted in semiannual evaluation, or Not related to	Work order (local reference) number	Summarize work requested	Date work order was submitted	Date work order was completed	Elapsed days from submission to completion
1	No	10285562	Electrical outlet trips breaker	8/21/17	3/5/18	196
2	No	11982006	Steam pipe needs insulated	9/21/17	2/12/18	144
3	No	70726380	Door sticking, needs adjustment (Rusted and swelled, beyond Repair and both need to be replaced)	6/21/18		
4	No	70726453	Exterior door difficult to open (Rusted and swelled, beyond repair. and both need to be replaced)	6/21/18		
5						

Table 3: Summary

Table #	Number of work orders entered	Average days elapsed
1	6	9
2	2	170

Comments (provide any additional information relevant to the numbers of days required for completion of the work orders submitted):

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VA SEMIANNUAL EVALUATION
of the
INSTITUTIONAL ANIMAL CARE AND USE PROGRAM AND FACILITIES
Part 1 – Checklist
Section B. Inspection of the Facilities

The Inspection of the Facilities focuses on a physical and visual evaluation of buildings, equipment, and the environment in which animals are maintained and utilized. Some of the items here appear similar to items included in Section A (Review of the Program), but the focus here (Inspection of the Facilities) is on what is actually observed in the animal facilities, while Section A focuses on what is intended or designed.

NOTE: The checklist is designed to prompt review according to regulatory requirements, and focuses on the minimum standards that must be met. The wording in the checklist is not to be interpreted as altering the regulatory requirements in any way, but represents guidance from the office of the CVMO. For specifics about the regulatory requirements and recommended best practices, the references provided in square brackets must be consulted:

"1200.01" refers to the "VHA Handbook 1200.01, Research and Development (R&D) Committee",
"1200.07" refers to the "VA Handbook 1200.07, Use of Animals in Research",
"PHS" refers to the "PHS Policy on Humane Care and Use of Laboratory Animals",
"9 CFR" refers to the "USDA Animal Welfare Act Regulations and Standards, Code of Federal Regulations, Title 9";
"US Govt Principle" refers to the "US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training", and
"Guide" refers to the National Research Council's "Guide for the Care and Use of Laboratory Animals", 8th edition, 2011

Instructions:

1) Enter identifying information in the header above:
   Double click in the header area.
   Then enter text after each ":"
      (Note: Federal regulations require that a new Review of the Program be completed every 6 months *[PHS (IV.B.1); 9 CFR (2.31(c)(1))]*, and a new Inspection of the Facilities be completed every 6 months *[PHS (IV.B.2); 9 CFR (2.31(c)(2))]*. The "Date of Semiannual Evaluation" is the date on which the last of the components of the semiannual evaluation was completed.)
   Double click in the document area to return to the main body of the form.
2) Enter the information requested below. The "▶" symbols indicate required information:

▶Date(s) of the most recent previous Inspection of the Facilities: **January 16, 2018**
▶Date(s) on which this Inspection of the Facilities was conducted: **July 17, 2018**

Names of voting IACUC members who participated in the Facility Inspection:
(The Facility Inspection team must include a minimum of two voting members of the IACUC [9 CFR (2.31(c)(3))]. Any non-members who also participate, at the discretion of the IACUC, may be listed in the second table.)

Name	Specific Role on IACUC	Date of Participation
▶		
(b)(6)		7/17/18
		7/17/18

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Non-Voting IACUC members who participated in the Facility Inspection:

Name	Title	Date of Participation
(b)(6)		7/17/2018
		7/17/2018

3) The IACUC must inspect semiannually all units of the animal care and use program, including the following:
all areas within the VA animal facilities;
all spaces outside the VA animal facilities where animals are housed for > 12 hours;
any areas where any procedure is performed on animals.

Identify each unit subject to inspection (press Tab in bottom right cell to add rows to the table):

Location (name of site, building name and room number, etc.)	**Species**	**Type of Space** (e.g., VMU, satellite, investigator laboratory) **and the Nature of the Procedures Performed** (e.g., housing, terminal surgery, behavioral training, etc.)	**Name and Role** (e.g., VMU Supervisor, PI) **of Responsible Individual**
(b)(6)	Mice / Rats/Hamsters	VMU – Housing / Behavior / Procedures	(b)(6)

4) For each item in the checklist, type "X" in the column that applies (shaded cells should not be used):

Not Applicable
Acceptable
Approved Departure (approved by the IACUC)
Minor Deficiency
Significant Deficiency
Could Not Evaluate (during this inspection)

The last line of each section of the checklist is designated "Other Observations", for documentation of relevant observations that are not directly addressed by the checklist items.

5) For each item marked as an Approved Departure, a Minor Deficiency, or a Significant Deficiency here (Part 1, Section B), provide details in Part 2 of this form.

6) Items that reflect changes in the 8th edition of the *Guide* are flagged as follows, and may require particular attention as the 8th edition is implemented.

‡ denotes a new "must" item

† denotes a new "should" item

I. Implementation of Institutional Policies

A. Performance of Work According to Protocol		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1150	Current versions of IACUC approved protocols are readily available to animal care staff as well as research staff.		X				

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1151	Animal research procedures (observed by the IACUC inspection team includes but is not limited to conduct of surgery, behavioral testing, training, exercise, administration of anesthetics and analgesics, etc.) are being performed according to the protocols approved by the IACUC. *[PHS (IV.C.1); Guide (p. 33-34)]*		X				
1152	Individuals observed working with animals are identified on the corresponding protocols approved by the IACUC.		X				
1153	Routine husbandry tasks observed are being performed according to documented SOPs.		X				

B. Addressing Concerns about Animal Welfare

		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**	**Could Not Evaluate**
1200	Contact information for responsible local and VA Central Office personnel are posted prominently in the animal facility for reporting of animal welfare concerns. *[1200.07 (8.k(2)); Guide (p. 24)]*		X				

C. Occupational Health and Safety

		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**	**Could Not Evaluate**
1250	Appropriate hazard signs and relevant safety protocols are posted in plain view, and the MSDSs are readily available, where specific hazardous agents are in use. *[1200.07 (Appendix C-8.h(1)-(2))]*		X				
1251	Wherever gas anesthetics are used, waste anesthetic gas is removed via a scavenging system or by another approved method. *[Guide (p. 21; 145)]*		X				
1252	Labels on safety equipment (e.g. eye wash, emergency shower, fume hoods, etc.) indicate that maintenance and certification are current. *[Guide (p. 20)]*		X				
1253	Good safety practices are evident as indicated by proper glass and sharps disposal, gas cylinders appropriately secured, proper separation of chemicals and wastes, etc. *[Guide (p.74)]*		X				
1254	Supplies are readily available for treatment of bites, scratches, and puncture wounds according to current CDC recommendations. *[Guide (p. 23)]*		X				
1255	Adequate supplies of appropriate attire and clean protective clothing, including disposable PPE (e.g. gloves masks, shoe covers, etc.) are readily available; soiled items are disposed of, laundered, or decontaminated according to approved facility procedures. *[1200.07(Appendix E-2.e) ;Guide (p. 20-22)]*		X				
1256	The IACUC inspection team determined that with regard to the use of hazardous agents, appropriate procedures, containment equipment, and personal protective equipment are used to safeguard personnel and animal health and are consistent (where applicable) with APHIS, USDA, and CDC Select Agent Regulations and other federal, state, and local regulations including security measures. *[1200.07 (Appendix E-2(l)); Guide (p. 20-22; 148-149)]*		X				

D. Other observations

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		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1300							

II. Physical Plant

A. General

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1350	Corridors are sufficiently wide and clear of obstacles so that personnel and equipment can move easily without impediment. *[Guide (p. 136)]*		X				
1351	Floor surfaces are moisture-resistant, nonabsorbent, and impact-resistant; floors are in good condition, without cracks, evidence of delamination or deterioration, of appropriate texture, and are clean and sanitized. *[Guide (p. 137-138); 9 CFR (Part 3, Standards)]*		X				
1352	Floors slope appropriately to drains; drains are filled with liquid, and those not in use for long periods are capped/covered. *[Guide (p. 138)]*		X				
1353	Wall and ceiling surfaces are smooth, moisture-resistant, nonabsorbent, impact-resistant, washable, and free of unsealed penetrations. These surfaces were found to be clean, sanitized according schedule, free of defects and evidence of water damage. *[Guide (p. 138-139); 9 CFR (Part 3, Standards)]*		X				
1354	Doors are adequately sized, fit tightly within their frames, are sealed to prevent vermin entry, and are in good repair; preferred features include self-closing mechanism, sweeps, recessed handles, and protective hardware. *[Guide (p. 137)]* Note: With the exception of doors with viewing windows that are needed for safety and other reasons, windows in animal facilities should generally be avoided.) *[Guide (p. 137)]*		X				
Heating, Ventilation, and Air-Conditioning (HVAC) System							
1355	Maintenance of temperature, humidity, and air pressure differentials within recommended ranges throughout the facility is documented. *[Guide (p. 43-47)]* ►List the document(s) Room Data Sheets / HVAC Report: **May, 2018**		X				
1356	HVAC reheat units serving animal rooms fail in the "off" position, as designed, to prevent over-heating of animals. *[1200.07 (7.a(2)(a))]*		X				
1357	Effective back-up mechanisms are in place to maintain temperatures and humidity within acceptable ranges in the event of an electrical outage or failure of the HVAC system in the animal research facility. *[Guide (p. 141)]*		X				
Power & Lighting							
1358	Moisture-resistant switches and outlets, and ground-fault interrupters, have been installed in wet areas (e.g. cage processing, aquatic holding areas, etc.) *[Guide (p. 141)]*		X				

1359	Light fixtures, timers, switches, and outlets are properly sealed to prevent vermin from being harbored in them. *[Guide (p. 141)]*		X				
1360	Protective covers are in place over light bulbs and light fixtures. *[Guide (p. 141)]*		X				
1361	In the event of a power failure, alternative or emergency power supply is available to maintain critical services. *[Guide (p. 141)]*		X				
Noise Control							
1362	Noise reduction practices are utilized. *[Guide (p. 49-50; 142)]* For example: • Entry doors from corridors to animal housing areas are closed when not in use. • Carts, racks, and other equipment are equipped with casters. • Noisy animals are grouped in one section of the animal facility. • Sound-generating equipment is selected and located to minimize disturbance to animals		X				
1363	Vibration dampening procedures are practiced where applicable. *[Guide (p. 142)]*		X				
Environmental Monitoring							
1364	Environmental conditions in animal holding spaces and other sensitive areas are monitored and verified by one or more mechanism or systems. *[Guide (p. 143)]*		X				

B. Facilities for Sanitization

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1400	A dedicated cage and equipment processing area of appropriate size and design (including safety features, traffic flow, utilities, egress, HVAC capacity, clean storage, etc.) is available and meets program needs.*[Guide (p. 143)]*		X				
1401	Appropriate safety precautions and equipment are in place and in use; including but not limited to protective clothing and equipment, posting of standard operating procedures and warning signage, eyewash/shower stations, and functioning safety devices to prevent trapping of personnel inside of walk-in equipment (e.g., cage/rack washers, bulk sterilizers). *[Guide (p. 143)]*		X				
1402	Cage wash temperatures and sterilizer effectiveness are monitored and appropriate records are maintained. *[Guide (p. 72-73)]*		X				

C. Storage Areas

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1450	Food and bedding, toxic or hazardous agents, and wastes are stored in separate designated areas. *[Guide (p. 141)]*		X				
1451	Food and bedding is stored in a vermin-free area and is protected from contamination. Temperature and humidity conditions are appropriate in food storage areas. *[Guide (p. 141)]*		X				

1452	Food stuffs/diets are obtained from reputable vendors and are managed to maintain quality *[Guide (p. 65- 67)]*: • Open bags of feed are stored in sealed, vermin-proof containers. • The storage area is clean and orderly; feed bags are stored off the floor on pallets, racks, or by other methods with adequate clearance from the wall to ensure good sanitation.		X				
1453	Bedding bags are stored off the floor on pallets, racks, or by other methods with adequate clearance from the wall to ensure good sanitation. Autoclaved bedding has been allowed to dry before use or storage. *[Guide (p. 69)]*		X				
1454	Refrigerated storage for animal carcasses and tissue waste is at <7°C (44.6 °F). *[Guide (p. 142)]*		X				
	D. Facilities for Aseptic Surgery						
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**	**Could Not Evaluate**
1500	Are located and designed to minimize traffic and/or contamination; the facilities include areas for surgical support, animal preparation, surgeon scrub, operating room and postoperative recovery that separate the related non-surgical activities from the operating room. Equipment and services needed to support the use of the surgery facility are available. *[Guide (p. 144-145)]*		X				
1501	Procedures are in place and have been implemented to assure effective sanitation of the operating room, surgical instruments and equipment, appropriate management and use of stored sterile supplies, scavenging of anesthetic gases, monitoring of drug inventory, and recordkeeping for anesthesia and postoperative care. *[Guide (p. 115; 122; 144-145)]*		X				
1502	Equipment needed to support aseptic surgery (e.g., autoclaves, anesthetic vaporizers, etc.) are in good repair and certifications are current. *[Guide (p. 20}*		X				
	E. Special Facilities *(include barrier, aquatics laboratory study areas, procedure areas, imaging, core service facilities ,etc.)*						
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**	**Could Not Evaluate**
1550	Where applicable, the facility/room has appropriate drug storage/monitoring, sharps disposal, anesthetic monitoring and scavenging, safety equipment/procedures (safety signage, eyewash stations, secured gas cylinders, etc.) and carcass disposal. *[Guide (p.19-21;73-74;115;120;122;134)]*		X				
1551	Specialized facilities have procedures and equipment in place to minimize contamination risk. *[Guide (p. 147-150)]*		X				
1552‡	Appropriate sensors and ventilation are provided for areas where cryogen gases are used or stored. *[Guide (p 147)]*	X					
1553	Aquatic housing areas feature water impervious surfaces, slip resistant floors, ground-faulted electrical receptacles or circuits, and HVAC capacity to maintain appropriate temperature and humidity control. *[Guide (p 150-151)]*	X					
	F. Ancillary Areas						

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		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1600	Showers, sinks, toilets, locker rooms, and break areas are available for personnel and are separate from animal holding or support areas. [*Guide (p. 19; 136)] (no shower facilities available)*		X				
1601	Space for administrative and supervisory personnel, including space for staff training and education are available and separate from animal holding or animal support areas. [*Guide (p 136)]*		X				

G. Security

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1650	Perimeter doors are closed and locked. *[1200.07 (7.i)]*		X				
1651	Security measures are in practice and mechanisms for controlling entry into the facility function appropriately. *[1200.07 (7.i); 1200.01.9.c; Guide (p. 23;151)]*		X				

H. Other Observations

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1700	Cages not in use need signage to "wash before use"				X		
1701							

III. Animal Environment, Housing, and Management

A. Physical Environment

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
Temperature, Humidity, and Ventilation							
1750	Temperature and humidity in animal rooms are within acceptable ranges. *Guide (p. 43)]*				X		
1751	Odors, ammonia levels, and drafts are all within acceptable limits; ventilation and air quality are adequate. *[Guide (p. 45)]*		X				
1752	The supply air to animal holding is 100 % outside air treated with appropriate filtration. Note: Exhaust air recycled into HVAC systems serving multiple rooms is a cross contamination risk and generally should be avoided. Exhaust air should be treated with at least 85-95% ASHRAE efficient filters prior to recycling. *[Guide (p. 45-47; 140)]*		X				
Illumination							
1753	Lighting in animal rooms is on appropriate diurnal cycles. *[Guide (p. 47)]*		X				

1754	The intensity, quality, distribution, and rates of change of intensity of the light are appropriate to the species in each room. *[Guide (p. 47-48)]*		X				
Noise							
1755	Radios and other equipment that produce unnecessary sound audible to the animals are not in use in animal rooms, except as required by approved protocols for research or enrichment. Vibration is minimized where possible. *[Guide (p. 49-50)]*		X				

B. Husbandry

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
General							
1800	Animals are appropriately separated by species and disease status. *[Guide (p.111)]*		X				
1801	Animal handling (observed by the IACUC inspection team) is appropriate to the species.		X				
1802	Room logs confirm that daily observation of each animal, as well as cage cleaning, feeding, and watering are performed at appropriate intervals. *[1200.07(7.c)]*		X				
1803	Special procedures (e.g., diet or water scheduling/restriction, prolonged restraint, etc.) are conducted as described in the IACUC approved protocols based on IACUC inspection team observations. *[1200.07 (Appendix D-1.u); PHS (IV.C.1); Guide (p. 27-33)]*		X				
Housing – Primary Enclosures							
1804†	Primary enclosures, cages, and shelters are appropriate (in terms of size, construction, floor space, height, etc.) for the species housed. *[9 CFR (Part 3, Standards); Guide (p. 51-57 and 55-63;* the *Ag Guide]* Note: • The recommended minimum rabbit cage height is16 inches; rabbit cages that are less than 16 inches in height may be used if the IACUC has determined through performance assessments that the cage is sufficient to meet the behavioral, physical, and physiological needs of the animal. *[Guide(p.58-59)]* • The recommended minimum floor space for a female mouse + litter is 51 in^2 ; trio breeding may be appropriate in a cage providing 75-82 in^2 of floor space; the IACUC should make this determination based on the outcome of performance based standards. *[Guide (p.56-58)]*		X				
1805‡	The primary enclosure allows the animal to express natural postures, turn around, access food and water, and rest away from urine and feces. *[Guide (p.56)]*		X				
1806	The primary enclosures (cages, tanks, pens, stalls, etc.) and accessories are clean, in good condition, and are free of rust and sharp edges; the enclosure provides safe species appropriate housing. *[Guide (p. 51)]*		X				
1807‡	Outdoor housing provides protection from extreme weather, conditions, the opportunity to retreat, and is adequately ventilated. *[Guide (p. 54-55)]*	X					
1808	Procedural laboratories that house animals for more than 12 hours meet the minimum standards for housing. *[1200.07 (Appendix E-3.b)]*	X					
Population Management							

Appendix 10: IACUC/OB Periodic Report

1809	Animal records (e.g., cage cards) include the following information, as appropriate *[Guide (p. 75-76); 9 CFR (2.35)]*: • Source of animals • Strain or stock (including genotype using standard nomenclature where applicable) • Name and contact information for PI • Protocol number • Pertinent dates (e.g., acquisition by facility, birth) • Number of individuals per group, when identified in groups • Age or weight • Gender • Individually identifiable features (e.g., markings, tattoos, ear • tags, neck chains, implanted microchips, etc.)		X				
1810	The IACUC inspection team determined that animal records are readily available, appropriately detailed, properly maintained, and accompany animals when transferred to another institution. *[Guide (p. 75-77)]*		X				
Behavioral Management							
1811	The IACUC inspection team determined that the environmental enrichment program is appropriate to the species, ages, and number of animals housed and is beneficial to and safe for the animals. *[Guide (p. 52-54)]*		X				
1812	Animals are housed in compatible social groups as appropriate; socially housed animals are able to escape or hide from aggressive animals, and have ready access to food and water. *[Guide (p. 51-60;63-65)]*		X				
1813	The IACUC inspection team reviewed the records of singly housed animals; *Guide* recommendations for singly housed animals are being followed. *[Guide (p. 64)]*		X				
1814	Based on the behavior observed by the IACUC inspection team, the animals are appropriately habituated to routine husbandry and experimental procedures. *[Guide (p. 64-65)]*		X				
Food							
1815	Each animal is fed uncontaminated, palatable, high quality food using a feed schedule and methods (that considers caloric management, delivery, and sanitation) appropriate to the species. *[Guide (pg. 65-67)]*		X				
Water							
1816	Each terrestrial animal has ready access to potable drinking water (quality based on periodic assessment) and the water distribution system is clean and appropriate to the species. *[Guide (p. 67-68)]*		X				
1817	For aquatic animals, the water quality is appropriate for the species. *[Guide (p. 78-79, 85)]*	X					
1818‡	In aquatic systems, chlorine, chloramines, chemical, and reactive bioproducts are removed or neutralized prior to use. *[Guide (p. 78, 86)]*	X					
1819‡	The biofilter of the aquatic life support system is of adequate size to process the bioload. *[Guide (p 80)]*	X					
Bedding							
1820	The bedding present in primary enclosures (where appropriate) is consistent with the species, facilitates good health, and meets scientific requirements. *[Guide (p. 68-69)]*		X				
Sanitation							

1821	Cleaning implements are designated for specific rooms or for areas at similar risk of contamination and are in good repair. *[Guide (p. 72)]*		X				
1822	Primary enclosures (including substrates and cage components), animal holding rooms, support spaces, etc. are cleaned and disinfected on a regular schedule consistent with the use of the area and nature of contamination. *[Guide (p 70 -72)]*		X				
1823	The effectiveness of sanitation methods/procedures are assessed and documented. *[Guide (p. 73)]*		X				

C. Animal Procurement and Transportation

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1850	Animals being transported are appropriately restrained, secured, and covered, to protect the health and safety of the animals and humans (passersby as well as personnel involved in the work with the animals), to minimize stress on the animals, and to ensure animal biosecurity. *[1200.07(Appendix E-3.a (15)); Guide (p. 107-109); 9 CFR (Part 3. Standards)]*		X				
1851	Promptly on receipt, animals are inspected by qualified personnel and moved to housing appropriate to the protocols for which they have been ordered. *[1200.07 (7.b(3)); Guide (p. 107-109)]*		X				
1852	The condition of animals on arrival indicates that transportation was consistent with USDA regulations and humane practices. *[Guide (p.107)]*		X				

D. Preventive Medicine

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1900	Based on the observations of the facility inspection team, animals are separated by species, source, health status, intended use (as appropriate) and after receipt, the animals are allowed a stabilization period. *[Guide (p. 109-112)]*		X				

E. Waste Disposal

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1950	Conventional, biological, and hazardous wastes are regularly collected, stored and disposed of through the use of safe handling and processing practices. *[Guide (p. 73-74)]*		X				
1951	Waste receptacles are leak-proof, labeled, cleaned regularly, and have tight-fitting covers. *[Guide (p. 73)]*		X				
1952‡	Hazardous wastes are rendered safe before removal from facility. *[Guide (p. 73-74)]*		X				
1953	Appropriate containers for sharps disposal are readily available in locations in which sharps are used, and are no more than 2/3 to 3/4 full. *[Guide (p. 74)]*		X				

F. Pest Control

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		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2000	A humane, effective, and documented pest prevention and control program (that includes rodents and insects) is in place; there is no evidence of pests in the facility. *[Guide (p. 74)]*		X				
2001	When it is necessary to use pesticides in animal holding areas, investigators are consulted in advance of pesticide use. *[Guide (p. 74)]*		X				

G. Medical Supplies

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2050	Non-pharmaceutical grade compounds identified during the inspection were confirmed to be associated with an IACUC approved protocol. *[PHS (FAQ F.4); Guide (31)]*	X					

H. Emergency, After Hours, Weekend, and Holiday Care

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2100	The review of log sheets confirm that animals are cared for by qualified personnel on weekends and holidays, as well as on regular weekdays. *[Guide ((p. 74); 9 CFR (2.33(b))]*		X				
2101‡	Posted contact information for veterinary staff and veterinary care entries in logs confirm that emergency veterinary care is available and provided as needed after hours, on weekends and holidays, as well as on regular weekdays. *[Guide ((p. 74;114); 9 CFR (2.33(b))]*		X				
2102	Telephone numbers of key personnel are readily accessible to police and fire agencies at all times. *[Guide (p. 74)]*		X				

I. Other Observations

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate

IV. Veterinary Medical Care

A. General

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2200	Animals are observed at least daily for signs of illness, injury or abnormal behavior by trained personnel. *[Guide (p. 112)]*		X				
2201	Visits by part-time veterinarians are documented in a log showing the date and time of each visit. *[1200.07 (Appendix E-2.f(9))]*		X				

B. Surgery

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2250	The IACUC inspection team determined that the recommendations of the *Guide* are followed for non-survival surgery (the surgical site is clipped, the surgeon wears gloves, the instruments and the surrounding area are clean). *[Guide (p. 118)]*		X				
2251	The IACUC inspection team determined that aseptic technique is used for all survival surgical procedures, and includes appropriate preparation of the animal (shaving and disinfection of the surgical site), preparation of the surgeon (scrubbing, use of sterile glove, gowns, etc.), and use of aseptic operative techniques; the aseptic technique procedures are appropriate for the species used. *[Guide (p. 118-119)]*		X				
2252	The IACUC inspection team determined that all surgical instruments and implants used in survival surgery are sterilized by steam, gas, or approved chemicals. Note: Alcohol is not a sterilant or a high-level disinfectant. *[Guide (p. 119)]*		X				
2254	The IACUC inspection team observed that for multiple consecutive rodent surgeries, personnel using hot bead sterilizers or liquid chemical sterilants for instrument sterilization take appropriate precautions to prevent thermal or chemical burns. *[Guide (p. 119)]*		X				
2255	The IACUC inspection team confirmed that the operating area is cleaned and disinfected prior to major survival surgery. *[Guide (p. 117)]*		X				
2256	The IACUC inspection team confirmed that appropriate intraoperative monitoring of anesthetic depth and physiological parameters is performed and documented by personnel. *[Guide (p. 119)]*		X				
2257	The IACUC inspection team confirmed that postoperative monitoring and care of appropriate intensity and frequency (includes anesthesia recovery, pain management, management of physiologic needs, assessment of overall well-being, wound healing, suture removal, etc.) was provided and documented by trained personnel. *[Guide (p. 119-120)]*		X				

C. Pain, Distress, Analgesia and Anesthesia

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2300‡	Drug storage and control practices comply with federal regulations for human and veterinary drugs. *[Guide (p. 115)]*		X				
2301‡	Analgesics and anesthetics (as well as other drugs) are used within their expiration date. *[Guide (p. 122)]*		X				
2302	Procedures for acquiring, using and storing anesthetics and analgesics are compliant with legal and safety standards. *[Guide (p. 115; 122)]*		X				
2303‡	Observation and/or record review indicates that before surgery begins, personnel ensured a surgical plane of anesthesia is attained. *[Guide (p. 122)]*		X				
2304	The IACUC inspection team determined that neuromuscular blocking agents are used in a humane and appropriate manner in accordance with the IACUC approved protocol. (*[Guide (p. 122-123)]*	X					

D. Euthanasia

Appendix 10: IACUC/OB Periodic Report

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2350	Personnel are competent in performing euthanasia methods that are appropriate to the animal's age and species and are consistent with AVMA Guidelines. Alternate methods of euthanasia, if used, are approved by the IACUC. *[Guide (p. 124); 9 CFR (2.31(d)(1)(xi))]*		X				
2351‡	Personnel confirm animal death after the euthanasia procedure. *[Guide (p.124)]*		X				
	E. Other Observations						
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**	**Could Not Evaluate**
2400							
2401							

▶Name of Medical Center: Cincinnati VA Medical Center Version
02/28/13
▶Station Number --------------: (b)(6
▶City, State------: Cincinnati Ohio
▶Date of Semiannual Evaluation: **January 16, 2018**

VA SEMIANNUAL EVALUATION
# of the
INSTITUTIONAL ANIMAL CARE AND USE
PROGRAM AND FACILITIES
Part 2 -- Table of Deficiencies and Departures

This form is for documenting the details about the observations noted in the checklists (Part 1, Sections A and B). Each deficiency, minor or significant, must be entered according to Instructions 2 and 3, below. Each "approved departure", as defined by OLAW, must be entered according to Instruction 4, below. The IACUC may also document on this form, at its discretion, other observations that are not deficiencies, and details about "deviations" that are not "departures", as defined by OLAW – these may be useful in addressing concerns raised by accreditation or regulatory agencies, or for monitoring purposes.

Instructions:

1) Enter identifying information in the header above:
    Double click in the header area.
    Then enter text after each ":"
        (Note: The "Date of Last Semiannual Evaluation" is considered to be the date by which both the Review of the Program and the Inspection of the Facilities were last completed. Federal regulations require that a new evaluation be completed no later than 6 months after the last evaluation.)
    Double click in the document area to return to the main body of Form 1.

2) Enter deficiencies with corrections that were still pending on the last report. Copy onto this form each item that was reported on Form 2 of the last semiannual evaluation, for which the correction was not yet completed when the last report was signed:
    Enter the date the deficiency was first noted in a semiannual evaluation.
    If the IACUC determines that a change in the scheduled date of correction is appropriate, (b)(6) (b)(6) add the new date below it.
    Enter the actual date when the correction of the deficiency was completed. If the work is not yet complete, leave the "Actual date of completion" blank, but include in the description any relevant information about progress to date.

Note: USDA requires the IACUC to report any failure to adhere to the plan and schedule for correction that results in a significant deficiency remaining uncorrected beyond the correction date set by the IACUC. The report must be submitted in writing within 15 business days of missing the correction date set by the IACUC, through the IO, to the Animal and Plant Health Inspection Service (APHIS) and any Federal agency funding the activity involved. Therefore, for the IACUC to change the correction date of a significant deficiency, it must review the justification for the change and approve a new correction date at a convened committee meeting prior to the original correction date.

3) Enter each new deficiency noted on Form 1 (Checklist), Parts A and B, of this report:
The date the deficiency was first noted.
The Part (A or B) and Item # on Form 1 to which it applies.
When applicable, indicate the location where the deficiency was noted.
A description of the specific deficiency -- Include sufficient detail for an outside observer to recognize when it has been corrected), a description of any underlying programmatic or systemic conditions that may have led to the deficiency, and a description of the plans both for correcting the deficiency and for addressing underlying factors so as to prevent recurrence. *[PHS (IV.B.3)]* Be sure to include the name of the individual who will be responsible for overseeing progress on the corrective action, on behalf of the IACUC. (The table will expand to accommodate the text entered.)
The severity of the deficiency (Minor [M] or Significant [S]), as indicated on Form 1.
The scheduled date of correction – enter the date by which the IACUC has determined that the correction should be completed.
The actual date when the correction of the deficiency was completed (leave blank if the work is not yet complete.)

4) Enter each "departure" from PHS Policy, including the provisions of the *Guide*, that has been approved by the IACUC. *[PHS (IV.B.3)]*

For any deviation from a general standard described in the *Guide*, the following series of test questions may be applied to determine whether the deviation is considered a "departure" by OLAW:

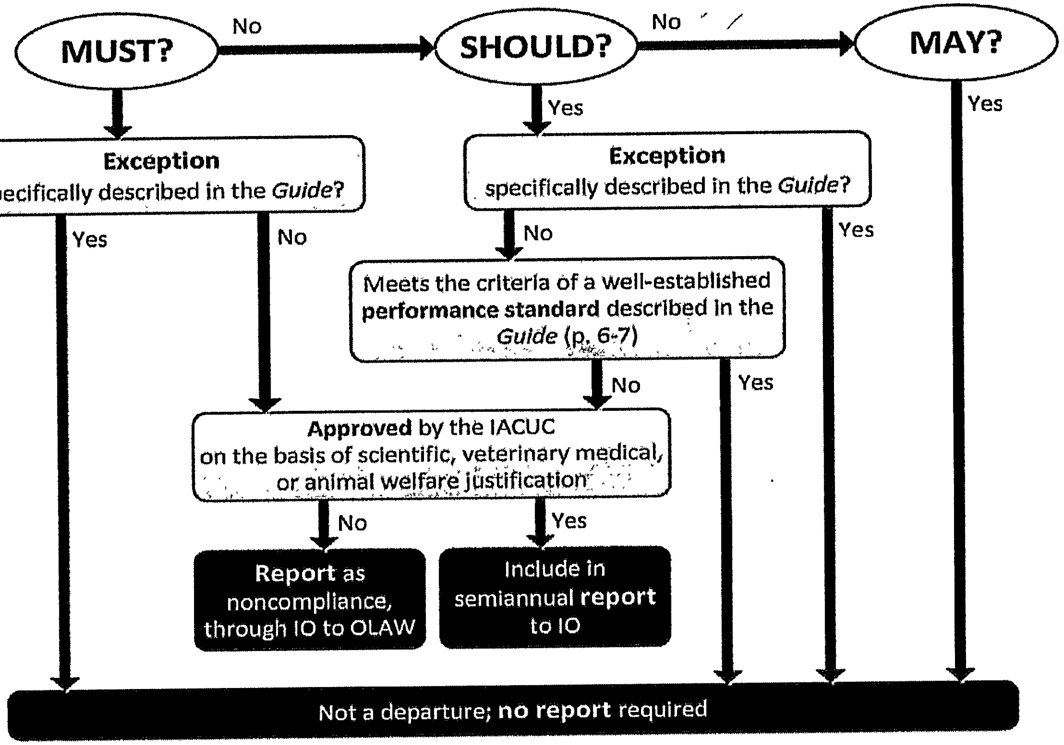
1. Does the Guide describe the general standard as a "May" standard? If so, this deviation from the general standard is NOT a "departure". Otherwise, for any "Should" or "Must" standard, proceed to the next question.

2. Does the Guide include an explicitly stated exception that allows for the deviation? If so, this deviation from the general standard is NOT a "departure. Otherwise, proceed to the next question.

3. Does the deviation meet a well-established performance standard for a "Should" standard, according to locally-defined and continuously monitored performance measures? If so, this deviation from the general standard is NOT a "departure". Otherwise, it IS a "departure", and may be approved by the IACUC only if justified on scientific, veterinary medical, or animal welfare grounds.

The test questions above are summarized in the following flow chart:

▶Name of Medical Center: Cincinnati VA Medical Center
02/28/13
▶Station Number -------------(b)(6)
▶City, State------: Cincinnati Ohio
▶Date of Semiannual Evaluation: **January 16, 2018**


MUST?
No
SHOULD?
No
MAY?
Yes
Exception specifically described in the *Guide*?
Yes
No
Exception specifically described in the *Guide*?
No
Yes
Meets the criteria of a well-established **performance standard** described in the *Guide* (p. 6-7)
No
Yes
Approved by the IACUC on the basis of scientific, veterinary medical, or animal welfare justification
No
Yes
Report as noncompliance, through IO to OLAW
Include in semiannual **report** to IO
Not a departure; **no report** required

For approved departures that are documented in Appendix 9 of an IACUC-approved ACORP, simply attach a copy of Appendix 9. (The Official Date of Approval in the header must be included, but be sure to redact the name of the PI and the protocol number assigned by the IACUC.) Enter below the table here the total number of Appendix 9 pages attached.

For approved departures that are not documented in an Appendix 9, enter the information into this form as follows:

▶Name of Medical Center: Cincinnati VA Medical Center Version 02/28/13
▶Station Number ---------------:(b)(
▶City, State------: Cincinnati Ohio
▶Date of Semiannual Evaluation: **January 16, 2018**

For “Original Date Noted”, enter the date of the IACUC meeting at which the departure was reviewed and approved..
[1200.07 (8.f(1)(d)2-3); PHS (IV.B.3) 9 CFR (2.31 (c)(3)); and Guide (p. 9]
If the departure relates to a specific item on Form 1, enter the Part (A or B) and Item # to which it applies.
If applicable, indicate the location to which the departure applies.
A description of the departure – include a summary of the grounds for granting approval for the departure.
Mark the “D” category, to indicate that the item details a departure.
Enter “N/A” in the columns for the “Scheduled Date of Correction” and the “Actual Date of Correction”.

5) Press “Tab” in bottom right cell to add rows to the table.

Original Date Noted	**Form 1**		**Location**	**Descriptive Details**	**Category**			**Scheduled Date of Correction**	**Actual Date Of Correction**
	Part	**Item #**			**M**	**S**	**D**		
Ongoing	B	1750	(b)(6)	Minor Deficiency from January 2016: The humidity in animal rooms are not within acceptable ranges according to the *Guide (p. 43).* Plan: New facilities or renovation of facilities is required to meet the set standards. ▶Person responsible for overseeing correction: (b)(6)	X			Estimated completion of the VMU in new research building is late 2018. Work on the HVAC for (b)(6) will begin after construction is complete and should be completed by December 2018.	

▶Name of Medical Center: Cincinnati VA Medical Center

Version 02/28/13

▶Station Number --------------: (b)(6

▶City, State------: Cincinnati Ohio

▶Date of Semiannual Evaluation: **January 16, 2018**

Ongoing	Section A: IIB	604	(b)(6)	Approved Departure: The environmental enrichment SOP addresses individually housed mice. Mice are housed singly if involved in fighting. Plan: All individually housed animals get enrichment unless PI scientifically requires reasons or veterinarian provides medical reason ▶Person responsible for overseeing departure: (b)(6)			X	N/A	N/A
Ongoing	Section B: IIA	522	(b)(6)	Approved Departure: Radio use SOP in place unless PI requests no radio ▶Person responsible for overseeing departure: (b)(6)			X	N/A	N/A
7-17-2018	Section B: H	1700	(b)(6)	Cages in storage not labeled with washed or autoclaved date ▶Person responsible for overseeing departure: (b)(6)	X			8/3/18	8/3/18

▶Total number of Appendix 9 pages attached: 5 (See attached Appendix 9's)

Appendix 10: IACUC/OB Periodic Report

VA SEMIANNUAL EVALUATION
of the
INSTITUTIONAL ANIMAL CARE AND USE PROGRAM AND FACILITIES

Part 3 – Post-Review Documentation

Instructions (The "►" symbols indicate required information):

1) Enter identifying information in the header above:
   Double click in the header area.
   Then enter text after each ":"
      (Note: The "Date of Semiannual Evaluation" is considered to be the date by which both the Review of the Program and the Inspection of the Facilities are completed.)
   Double click in the document area to return to the main body of Form 1.

2) ►Enter the date of the most recent previous Semiannual Evaluation: **1/16/2018**

3) Enter the names of all voting members of the IACUC, and identify the member who fills each required role on the committee, in the table in Section D, below. If any alternate members have been appointed, enter the name of each alternate member in the square brackets (e.g., "[Alt: John Smith]") below the name of each primary member for whom the alternate may serve. Only one member, the primary or the designated alternate, should sign in any one row of the table. (Press "Tab" in bottom right cell to add rows to the table.)

4) Complete Sections A-F, below.

A. SUMMARY OF SEMIANNUAL EVALUATION. Summarize the results of this semiannual evaluation, including an analysis of the implications of the results for the animal research program as a whole. The summary should:

- Note the total number of "departures" from PHS policy, including the provisions of the *Guide*, that have been approved by the IACUC.
    - The Cincinnati VA IACUC conducted the semi-annual evaluation of our animal research program on Tuesday July 17th, 2018. At this time, our committee went over the previous report to ensure any deficiencies had been addressed or resolved as well as reviewed Part 1 section A, of the checklist. The evaluation of the animal facility included 3 members of our committee and our program analyst.

Appendix 10: IACUC/OB Periodic Report

Once the inspection was completed Part 1 section B and Part 2 of the checklist was prepared for the committee to review at the August 21st 2018 meeting. Our findings are as follows:

The total number of departures, included in approved ACORP's: 5, see attachment to the checklist with full Appendix 9 documentation.

The total number of ongoing departures, addressed by SOP's or included in our program: 3, which are listed in Part 2, 5 Table of Deficiencies and Departures, as "Ongoing" departures that have been discussed and approved by our committee as part of our program.

- Provide summary overviews of the programmatic and facility deficiencies
    - If there were no deficiencies, include a statement to this effect in the report.
    - If deficiencies were identified, evaluate the overall number and severity of the deficiencies, and what the number and severity indicate about the quality of the program and facilities (refer to the complete list provided in Part 2 – Table of Deficiencies and Departures).

During the facility inspection, the team noted 1 ongoing deficiency and 2 current, minor deficiencies (see items listed in Part 2 – table of deficiencies).
The ongoing minor deficiency has been addressed many times. The humidity in the animal rooms is not always within range, depending on the season (low in winter, high in summer) due to the antiquated HVAC system that controls the animal rooms. The facilities management and veterinarian keep a close eye on the health of the animals and have not seen any health concerns potentially caused by the humidity levels, but very easily could become an issue. This has been presented to the Hospital facilities department many time and is currently on the list of projects to be completed to upgrade/replace the HVAC for the animal rooms. There is no specific timeline as to when this project will take place.
The minor deficiencies were both involving labeling suggestions (clean caging)

- Comment on any patterns or trends suggested by the observations during this semiannual evaluation and also in the light of previous semiannual reports.
The only ongoing trend is the Humidity levels being inconsistent, which has been addressed in the previous section.

- Acknowledge any laudable aspects of the overall animal care and use program (i.e., related to the program, facility, or personnel).
It is noted by the inspection team, during this inspection and previous inspections, the facility is always very clean, orderly and well-kept by the animal care staff.

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- Provide a concluding paragraph that: (1) assesses the institution's overall compliance with applicable PHS Policy, the *Guide*, the AWA, and VA Policy; (2) provides recommendations to the IO; and (3) highlights any other pertinent information the IO should be made aware of.
  The Cincinnati VA VMU and animal research program strives to meet and exceed compliance with all oversite policies. The program has consistently passed AALAC inspections with flying colors and the Semi-Annual IACUC reviews have very little to report. Our administrative and animal care teams work together to ensure we have an exceedingly compliant program. Our main recommendation to the IO is that the HVAC system needs to be high on necessary upgrades list as AHU 21 (air handling) is very old and the potential for failure is very high. The IACUC asks this to be addressed with an update on where the replacement project stands on the priorities list. The failure of this system could be devastating to the ongoing research projects. In addition, the committee would like to emphasize that the new facility (b)(6) is over 2 years behind in its completion date. If the final issues are addressed with the new facility, allowing us to take ownership, there would be the safety net of having (b)(6) in use in case of an HVAC failure in (b)(6).

B. DOCUMENTATION of MINORITY OPINION(S). *Any participant in the semiannual evaluation who wishes to provide a minority opinion MUST be allowed to do so [1200.07 (8.f(1)(d)4); PHS (IV.E.1.d); 9 CFR (2.31(c)(3))].* Did any participant submit a minority opinion?

_______ Yes ____X____ No If "yes", fill out section E below.

C. Statement of AAALAC Accreditation *[PHS (IV.B.3)].* Are all VA animals housed or used only in facilities that are part of an AAALAC accredited program?

__X__ Yes. If yes, describe the accreditation as indicated below.

Identify the AAALAC accredited program: Cincinnati VA Medical Center / VISN 10

Give the date of the most recent achievement of Full Accreditation: **July 5, 2016**

____ No. If no, describe the components that are not Fully Accredited, as indicated below.

If VA animals are housed or used at an affiliate institution that is not AAALAC accredited,

Identify the affiliate:

Give the date on which the CVMO approved this arrangement:

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If VA animals are housed or used at an institution where the AAALAC accreditation status is other than Full Accreditation,

Identify the institution:

Give the current accreditation status:

Describe briefly the current status of the institution in the process of regaining full accreditation: N/A

D. DOCUMENTATION of REVIEW and APPROVAL by IACUC MEMBERS. *A majority of all voting members (not merely a majority of a quorum) must approve and sign the report [1200.07 (8.f(1)(e)); 9 CFR (2.31(c)(3))]. The report must be completed within one month of the date of the semiannual evaluation to facilitate timely progress on any corrective actions required.*

The undersigned verify that we
1) have reviewed and approved Forms 1 (Checklist, Parts A and B) and 2 (Table of Deficiencies and Departures),
2) have read any minority opinions appearing in item E of this report, and
3) hereby authorize IACUC representatives to review this report with the Medical Center Director:

TYPED NAME	ROLE ON IACUC	SIGNATURE	DATE
(b)(6)		▲	
		▲	
		▲	
		▲	

(b)(6)	▶	
	▶	
	▶	
	▶	
	▶	
	▶	
	▶	

E. MINORITY OPINION(S). If part B is checked "yes", provide the typed minority opinion(s) here:

F. COMMUNICATION WITH DIRECTOR OF THE FACILITY. After a majority of all voting IACUC members approve the report and indicate their approval (in Section D, above) by signatures next to their typed names and roles on the committee, *the report must be discussed personally with the facility Director by at least one voting member of the IACUC, representing the committee. It is recommended that the Attending Veterinarian and the IACUC Chair meet with the Director (any voting member of the IACUC who wishes to participate must be allowed to do so). It is a best practice for the ACOS for R&D and/or the AO for R&D to attend as well. After the meeting, the Director must sign the reporting indicating that he/she has reviewed it. [1200.7(8.f(1)(e))].* **Note: the Director's signature only indicates awareness of the contents of the report, and does not**

Appendix 10: IACUC/OB Periodic Report

imply agreement with the report or satisfaction with the corrective measures proposed. The report may not be altered after it has been signed by a majority of the voting IACUC membership, but any disputed items may be discussed in a cover memo.

Certification: By my signature, I acknowledge receipt of this report, and verify that I have personally discussed its contents with the representatives of the IACUC.

Typed Name of Director	**Signature**	**Date**
(b)(6)	▶	▶

G. FINAL PROCESSING

A signed copy of the complete report (including Parts 1, 2, and 3) must be sent through the ACOS/R&D and Medical Center Director to the CVMO within 60 days of the date of approval and signature by a majority of the voting IACUC members. The R&D Committee should review the approved report as an item of business, but R&D approval is not required before submission of the final document to the CVMO. Send a copy including all signatures as a hard copy to (b)(6) Atlanta VA Medical Center, Research Service-151V, 1670 Clairmont Road, Decatur, GA 30033, or as an email attachment to (b)(6) @va.gov and (b)(6) @va.gov . The original must be retained for at least three years.

*** Signed copy with Appendix 9 attachments on site***

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Summarize the heating, ventilation and air conditioning (HVAC) systems for each animal facility, ***including all satellite facilities***. Include ***all animal holding rooms*** (including satellite holding rooms), surgical facilities, procedure rooms, and support spaces integral to animal facilities (e.g., cage wash, cage and feed storage areas, necropsy, treatment).

Location/Building/Facility: (b)(6)

In the text box below, provide a general description of the mechanical systems used to provide temperature, humidity and air pressure control. Include details such as:

- the source(s) of air and air recirculation rates if other than 100% fresh air
- treatment of air (filters, absorbers, *etc.*)
- design features such as centralized chilled water, re-heat coils (steam or hot water), individual room vs. zonal temperature and relative humidity control, the use of variable air volume (VAV) systems and other key features of HVAC systems affecting performance
- features that minimize the potential for adverse consequences to animal well-being (such as re-heat coils that fail closed or that are equipped with high-temperature cut-off systems), and
- how room temperature, ventilation, and critical air pressures are monitored and maintained in the event of a system or component failure, including notifying appropriate personnel in the event of a significant failure that occurs outside of regular working hours and/or other management systems used to respond to alerts or failures.

- AHU 31 which serves (b)(6) animal rooms and (b)(6) AHU, supplies 100% outside air.
- MERV 8 pre-filter and MERV 14 after filter in the AHU. There is a filter contract that changes out these filters when needed.
- AHU 31 has its own dedicated chiller or can receive chilled water from the Central Plant. There are hot water re-heat coils on the VAV boxes. There is a temperature sensor in each animal room that controls the VAV box and re-heat coil. Humidity levels are controlled by a zone humidity sensor. The Aircuity Optinet system measures CO2, TVOCs, and Particulate Levels in each animal room (in addition it measures humidity in building 14). If the monitored items exceed threshold values, the Aircuity Optinet system increases the airflow in the room to bring levels to below threshold levels.
- The re-heat coils fail closed.
- The Building Automation System (Johnson Controls Metasys) sends emails and text messages to the Maintenance Supervisor if an item on its system is in alarm.

Above describes the Animal (b)(6) All other rooms in (b)(6) are served by AHU 30 which is also a 100% outside air unit. This unit is a dual duct system and serves mixing boxes in each individual room. AHU 30 is served by the Main Chiller plant. It

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

also has the Aircuity Optinet system in most rooms. JCI Metasys controls all mixing boxes off of AHU 30 and sends out alarms via text and email to the Maintenance Supervisor.

In the Table below, provide room-specific information requested. For each room within this location, indicate use, including the species for animal housing rooms. *Measurement of air exchange rates and verification of relative pressure within animal housing rooms (excluding rooms housing aquatic species only) and cage washing facilities must be completed* ***within the 12 months preceding completion of this Program Description.*** Air exchange rates may be important to maintain air quality in other areas; *however, measurements may be left at the discretion of the institution.* Information may be provided in another format, providing all requested data is included. **[*Note*: Please remove the examples provided in the Table below.]**

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
(b)(6)	Animal Housing	70.8°F	Y	Low/critical 64/62 High/Critical 81/83	Y	-	11.0	5/2018
	Animal Housing	71°F	Y	Low/critical 64/62 High/Critical 81/83	Y	-	8.5	5/2018
	Animal Housing	70°F	Y	Low/critical 64/62 High/Critical 81/83	Y	-	9.8	5/2018
	Animal Housing	70.6°F	Y	Low/critical 64/62 High/Critical 81/83	Y	-	10.5	5/2018
	Animal Housing	71°F	Y	Low/critical 64/62 High/Critical 81/83	Y	-	10.1	5/2018
	Animal Housing	70°F	Y	Low/critical 64/62 High/Critical 81/83	Y	-	10.1	5/2018
	Animal Housing	70°F	Y	Low/critical 64/62 High/Critical 81/83	Y	-	20.7	5/2018
	Animal Housing	70°F	Y	Low/critical 64/62 High/Critical 81/83	Y	-	10.2	5/2018
	Clean Storage	N/A	N	N/A	Y	+	19.8	5/2018

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Room No.	**Specific Use**	**Temperature Set-Point** (define units)	**Electronic / Emergency Monitoring of Temperatures** (Y/N)	**Alert/Alarm Temperature Ranges** (if applicable; define units)	**Humidity Control** (Y/N)	**Relative Pressure**	**Air Exchange Rate** (per hour)	**Date Verified / Measured**
		(settings to be verified)					**(values to be measured)**	
(b)(6)	Dry Storage	N/A	N	N/A	Y	-	50.2	5/2018
	Clean Procedure	N/A	N	N/A	Y	+	18.8	5/2018
	Dirty Cage Dump	N/A	N	N/A	Y	-	44.6	5/2018
	Necropsy Room	N/A	N	N/A	Y	+	22.6	5/2018
	Feed/Bedding	N/A	N	N/A	Y	+	21.5	5/2018
	Animal Housing	Not in use	Y	N/A	Y	-	10.0	5/2018
	Large Animal Housing (not in use)	70°F	Y	Low/critical 64/62 High/Critical 81/83	Y	-	22.6	5/2018
	Bottle Wash	N/A	N	N/A	Y	+	19.0	5/2018
	Ante/Coat Room	N/A	N	N/A	Y	+	28.0	5/2018

[Create additional rows by pressing TAB in the bottom-right box.]

Copy and repeat the Description and Table for each location, including all satellite housing locations.

Appendix 12: Aquatic Systems Summary – Part I

Please summarize water management and monitoring information programs for each animal facility, including all satellite facilities, rooms, enclosures. The following key will assist you in completing the form:

(1) List location of aquaria, including outdoor enclosures (ponds or outdoor tanks). If indoors, list building and room number. Note that all species housed at the same location and maintained via the same design and monitoring may be listed in the same row.
(2) Please indicate if embryonic (E), larval (L), juvenile (J) or Adult (A)
(3) Group tanks (ponds, outdoor tanks, multiple aquaria) are arranged as arrays with shared water supply; individual aquaria have exclusive water handling systems.
(4) Indicate water type, e.g., fresh, brackish, or marine.
(5) Indicate water pre-treatment, e.g., dechlorination, rough filters.
(6) Indicate water circulation, e.g., static, re-circulated, constant flow, or some combination of these. If applicable, indicate water exchange frequency and amount (percentage).
(7) Provide a key word for filtration employed, e.g., biological, chemical, mechanical, and type (e.g., mechanical-bead filter). A diagram may be provided showing the flow of water, filtration, source of "make-up" water and amount replaced daily.

Part I No Aquatics

Location (1)	Species (2)	System Design					
		Group / Individual (3)	Water Type (4)	Pre-treatment (5)	Circulation (6)	Filtration (7)	Disinfection (e.g., UV, ozone)

Note: Records of equipment maintenance (filter changes, UV bulb changes, probe changes, calibrations, *etc.*) should be available for review.

[Create additional rows by pressing TAB in the bottom-right box.]

Appendix 12: Aquatic Systems Summary – Part II

The following key will assist you in completing this form:
(1) In these columns, please indicate monitoring frequency, e.g. daily, weekly, monthly or other point sampling frequency; continuous/real time, or none, if applicable. Also indicate method of control (heaters versus room HVAC, hand versus auto dosing, etc.).
(2) Indicate other parameters and their monitoring frequency, e.g., alkalinity, total hardness, conductivity, chlorine/chloramine.

Part II **No Aquatics**

Monitoring ***Indicate in the boxes below the frequency of monitoring and method of control for the following parameters. (1)***									
Location (from Part I)	**Temperature**	**Salinity**	**pH**	**NH_4**	**NO_2**	**NO_3**	**Dissolved O_2**	**Total Dissolved Gases**	**Other. Please List (2):**

Note: This information may be provided in another format, provided that all requested data is included.

[Create additional rows by pressing TAB in the bottom-right box.]

Appendix 13: Primary Enclosures and Animal Space Provisions

Please complete the Table below considering performance criteria and guiding documents (e.g., Guide, Ag Guide, ETS 123 and/or other applicable standards) used by the IACUC/OB to establish adequacy of space provided for all research animals including traditional laboratory species, agricultural animals, aquatic species, and wildlife when reviewing biomedical, field, and agricultural research studies.

Species	**Dimensions of Enclosure (cage, pen, tank*, corral, paddock, etc.)**	**Maximum Number Animals / Enclosure**	**Guiding Document Used to determine the Institution's Space Standards (Guide, Ag Guide, ETS 123, Other)**	**Enclosure Composition & Description****
Mouse	11" x 7" x 5"h	4 adults/cage; 2 adults with 1 litter	*Guide for the Care and Use of Laboratory Animals* (Eighth edition)	Solid bottom polycarbonate, polyetherimide or polysulfone shoebox cage with stainless steel wire bar lid and filter top: Static microisolator cage
Mouse	12.5"x7"x5"	5 adults/cage; 2 adults with 1 litter	*Guide for the Care and Use of Laboratory Animals* (Eighth edition)	Solid bottom polycarbonate, polyetherimide or polysulfone shoebox cage with stainless steel wire bar lid and filter top: individually–ventilated cage
Rat	18"x10"x8"	2 adults/cage; 2 adults with 1 litter/cage; 3	*Guide for the Care and Use of Laboratory Animals* (Eighth edition)	Solid bottom polycarbonate, polyetherimide or polysulfone shoebox cage with stainless steel wire bar tops, open- top or static microisolator cage
Rat	24"x17"x8"	6	*Guide for the Care and Use of Laboratory Animals* (Eighth edition)	Static microisolator cages that can be divided into two areas
Hamster	18"x10"x8"	We only house 2 per cage to prevent fighting	*Guide for the Care and Use of Laboratory Animals* (Eighth edition)	Solid bottom polycarbonate, polyetherimide or polysulfone shoebox cage with stainless steel wire bar tops, static microisolator cage

*For aquatic species, provide tank volume.

**Include descriptors such as open-topped, static microisolator, individually-ventilated cage systems (IVCS).

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Please describe the cleaning and disinfection methods in the Table below. Note the washing/sanitizing frequency and method for each of the following:

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
Micro-environment				
Solid-bottom cages (static)	Rack washer	1-3 x/week	Alka-det2 - Chlorinated Alkaline detergent and/or Acid Power - phosphoric acid washing detergent	Mouse cages autoclaved with bedding in them and rat cages are bedded with autoclaved bedding
Solid-bottom cages (IVC)	Rack washer & autoclave	1-2 x/week	Alka-det2 - Chlorinated Alkaline detergent and/or Acid Power - phosphoric acid washing detergent	Autoclaved with bedding in them
Suspended wire-bottom or slotted floor cages	n/a			
Cage lids	Rack washer	2x/month	Alka-det2 - Chlorinated Alkaline detergent and/or Acid Power - phosphoric acid washing detergent	
Filter tops	Rack washer	2x/month	Alka-det2 - Chlorinated Alkaline detergent and/or Acid Power - phosphoric acid washing detergent	
Cage racks and shelves	Rack washer	Monthly	Alka-det2 - Chlorinated Alkaline detergent and/or Acid Power - phosphoric acid washing detergent	

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
Cage pans under suspended cages	n/a			
Play pens, floor pens, stalls, etc.	Foaming sprayer	2x/month		Or as cage is empty
Corrals for primates or outdoor paddocks for livestock	n/a			
Aquatic, amphibian, and reptile tanks and enclosures	n/a			
Feeders	Rack washer	2x/month	Alka-det2 - Chlorinated Alkaline detergent and/or Acid Power - phosphoric acid washing detergent	
Watering devices	Rack washer, manually	1-2x/week	Alka-det2 - Chlorinated Alkaline detergent and/or Acid Power - phosphoric acid washing detergent	Bottles 1/week, water system sanitized every 3 months, sippers wiped with clidox weekly
Exercise devices and manipulanda used in environmental enrichment programs, etc.	Rack washer	Weekly - 2x/month	Alka-det2 - Chlorinated Alkaline detergent and/or Acid Power - phosphoric acid washing detergent	
Transport cages	n/a			
Operant conditioning & recording chambers, mechanical restraint	Hand washing	After use	Clidox spray and wipe off	

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
devices (chairs, slings, etc.)				
Euthanasia chambers	Hand washing	After use	Rinse in sink and spray and wipe down with Clidox	
Macro-Environment				
Animal Housing Rooms: When room is empty, foamed with high pressure sprayer				
Floors	Sweep/hose/mop, foam, high pressure washer	Sweep/Mop – up to 5 times a week	Quaternary ammonium Sanitizer	Sanitized with room monthly
Walls	Manually	Monthly	Quaternary ammonium Sanitizer	
Ceilings	Manually	Monthly	Quaternary ammonium Sanitizer	Light washing, dry wall
Ducts/Pipes	Manually	Monthly	Quaternary ammonium Sanitizer	
Fixtures	Manually	Monthly	Quaternary ammonium Sanitizer	
Corridors:				
Floors	Mop	3-5 x/week	Quaternary ammonium Sanitizer	
Walls	Manually	Every 2 months	Quaternary ammonium Sanitizer	
Ceilings	Manually	As needed	Quaternary ammonium Sanitizer	Drop ceilings get light washing when needed

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
Ducts/Pipes	Manually	Quarterly	Quaternary ammonium Sanitizer	
Fixtures	Manually	Quarterly	Quaternary ammonium Sanitizer	
Support Areas (e.g., surgery, procedure rooms, etc.); complete for each area:				
Floors	Manually	2-5 x/week and after use	Quaternary ammonium Sanitizer	
Walls	Manually	Monthly	Quaternary ammonium Sanitizer	
Ceilings	Manually	As needed	Quaternary ammonium Sanitizer	
Ducts/Pipes	Manually	Quarterly	Quaternary ammonium Sanitizer	
Fixtures	Manually	Quarterly	Quaternary ammonium Sanitizer	
Implements (note whether or not shared):				
Mops	Individual room mops	Monthly	Run through Laundry	Change mop water 2-3 x/week
Mop buckets	Individual room buckets	Monthly	Cage washer	
Aquaria nets	n/a			
Other	Individual dust pans and brooms	Quarterly	Quaternary ammonium Sanitizer	
Other:				
Vehicle(s)	N/A			

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	**Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)**	**Washing/ Sanitizing Frequency**	**Chemical(s) Used***	**Other Comments (e.g., autoclaved)**
Other transport equipment (list)	N/A			

*Please provide chemical, not trade name.

Appendix 15: Facilities and Equipment for Sanitizing Materials

In the Tables below, summarize the facilities and equipment used to sanitize animal related equipment (tunnel washer, bottle washer, rack washer, bulk autoclave, hand-washing area, bedding dispensing unit, *etc.*). Note that some descriptions may be combined if all share identical features (e.g., all rack washers).

[*Note*: Please remove the examples provided in the Table below.]

Building	Room No.	Equipment Type	Safety Feature(s)	Methods of Monitoring Effectiveness
(b)(6)		Rack washer (s)	Emergency "off" button; labeled exit door, de-energizing cord on both sides, instructional signage	Guarantee 180-degree hot water rinse; temperature-sensitive tape used weekly; ATP test swabs for caging and components monthly and service contract performs routine and preventative maintenance quarterly
		Bottle Washer	Emergency Off button	Guarantee 180-degree hot water rinse; temperature-sensitive tape used weekly; ATP test swabs for caging and components monthly
		Bottle Washer		Guarantee 180-degree hot water rinse; temperature-sensitive tape used weekly; ATP test swabs for bottles monthly
		Bulk autoclave	Emergency "off" button and lock out key	Temperature sensitive tape, sterilizer indicator strip used during each cycle, biological indicator run monthly, and service contract performs routine and preventative maintenance quarterly
		Pass through autoclave	Emergency "off" button and lock out key	Temperature sensitive tape, sterilizer indicator strip used during each cycle, biological indicator run monthly, and service contract performs routine and preventative maintenance quarterly

[Create additional rows by pressing TAB in the bottom-right box.]

Appendix 16: Lighting Summary

Using the Table below, summarize the lighting system(s) for the animal housing facility(ies). For each species or holding room type, list light intensity (range), construction features (e.g., water resistance), photoperiod (light:dark) and control (e.g., automatic versus manual, phasing). For systems automatically controlling photoperiod, describe override mechanisms (including alarms, if applicable).

Location:	**Buildings 14 and 15**

Room Type(a)	**Light Intensity Range**	**Lighting Fixture Construction Features**(b)	**Photo-period** (hrs)(c)	**Photoperiod and Lighting Control**	**Override Mechanisms** (if applicable)
Rodent Holding Rooms	130-300 lux	Surface mounted, water resistant	12:12	Light timers in 15, controlled by watchdog system in 14	Can turn on emergency or red lighting (bldg. 14) at switch.
Surgery/Procedure Room	Up to 500 lux (under spot lamp)	Recessed, water resistant; arm-mounted, water resistant	N/A	N/A	N/A
Necropsy	Not measured	Recessed, water resistant; arm-mounted, water resistant	N/A	N/A	N/A
Cage-Washing Room	Not measured	Recessed, water proof	N/A	N/A	N/A

[Create additional rows by pressing TAB in the bottom-right box.]

(a) A list of each room is not needed; group or cluster rooms by species or function

(b) Include such features as water resistance, red lighting, *etc.*

(c) Note if light cycle inverted/reversed.

Repeat Location and Table as necessary for each location, including satellite housing locations.

Appendix 17: Satellite Housing Facilities

Note: In the Program Description Section 2. IV. (Physical Plant), item C., describe the criteria used to determine a "Satellite Animal Holding Area." In the Table below, summarize these animal housing areas. Note that the total square footage for all each of these must also be included in the Summary of Animal Housing and Support Sites **(Appendix 2)**, and applicable information regarding these areas included in the Heating, Ventilation, and Air Conditioning (HVAC) Summary (**Appendix 11**) and Lighting Systems Summary (**Appendix 16**).

Not Applicable

Building	**Room(s)**	**Person Responsible**	**Species Used**	**Approximate Area (ft^2 or m^2) Devoted to Housing**	**Maximum Period of Stay**	**Purpose / Rationale / Justification**	**Construction Features and Finishes**

[Create additional rows by pressing TAB in the bottom-right box.]